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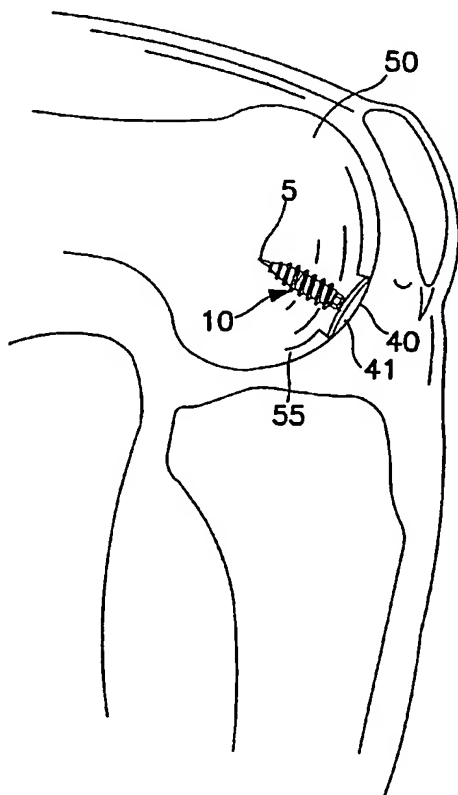
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(54) Title: SYSTEM AND METHOD FOR JOINT RESURFACE REPAIR



(57) Abstract: A generic bone implant, or set of standardized implants, is created based on using a guide device to develop an axis normal to an articular surface of bone and collecting only one or two data points. A generic cutting tool is used to cut the bone to a point where a generic implant can be used. Several improved tools relating to the procedure for using such an implant, as well as methods for using implants consistent with the invention are further described, including: single-axis and biaxial drill guide tools and methods, generic single-axis implant methods and devices, generic biaxial implant methods and devices, tools and methods for holding or delivering an implant, removal or revision tools and methods, digital measuring systems and methods, and set of measuring gauges for determining the appropriate implant dimensions.

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SYSTEM AND METHOD FOR JOINT RESURFACE REPAIR

FIELD OF THE INVENTION

This invention relates to devices and methods for the repair of defects that occur in articular cartilage on the surface of bones, particularly the knee.

BACKGROUND OF THE INVENTION

Articular cartilage, found at the ends of articulating bone in the body, is typically composed of hyaline cartilage, which has many unique properties that allow it to function effectively as a smooth and lubricious load-bearing surface. However, when injured, hyaline cartilage cells are not typically replaced by new hyaline cartilage cells. Healing is dependent upon the occurrence of bleeding from the underlying bone and formation of scar or reparative cartilage called fibrocartilage. While similar, fibrocartilage does not possess the same unique aspects of native hyaline cartilage and tends to be far less durable.

Hyaline cartilage problems, particularly in knee and hip joints, are generally caused by disease such as occurs with rheumatoid arthritis or wear and tear (osteoarthritis), or secondary to an injury, either acute (sudden), or recurrent and chronic (ongoing). Such cartilage disease or deterioration can compromise the articular surface causing pain and further deterioration of joint function. As a result, various methods have been developed to treat and repair damaged or destroyed articular cartilage.

For smaller defects, traditional options for this type of problem include non-operative therapies (e.g., oral medication or medication by injection into the joint), or performing a surgical procedure called abrasion arthroplasty or abrasion chondralplasty. The principle behind this procedure is to attempt to stimulate natural healing. At the defect site, the bone surface is abraded, removing approximately 1 mm. or less using a high-speed rotary burr or shaving device. This creates an exposed subchondral bone bed that will bleed and will initiate a fibrocartilage healing response. Although this

1 procedure has been widely used over the past two decades and can provide good short
2 term results, (1-3 years), the resulting fibrocartilage surface is seldom able to support
3 long-term weight bearing, particularly in high-activity patients, and is prone to wear.

4 Another procedure, referred to as the "microfracture" technique, incorporates
5 similar concepts of creating exposed subchondral bone. During the procedure, the
6 cartilage layer of the chondral defect is removed. Several pathways or "microfractures"
7 are created to the subchondral bleeding bone bed by impacting a metal pick or surgical
8 awl at a minimum number of locations within the lesion. By establishing bleeding in the
9 lesion and by creating a pathway to the subchondral bone, a fibrocartilage healing
10 response is initiated, forming a replacement surface. Results for this technique are
11 generally similar to abrasion chondralplasty.

12 Another known option to treat damaged articular cartilage is a cartilage transplant,
13 referred to as a Mosaicplasty or osteoarticular transfer system (OATS) technique. This
14 involves using a series of dowel cutting instruments to harvest a plug of articular cartilage
15 and subchondral bone from a donor site, which can then be implanted into a core made
16 into the defect site. By repeating this process, transferring a series of plugs, and by
17 placing them in close proximity to one another, in mosaic-like fashion, a new grafted
18 hyaline cartilage surface can be established. The result is a hyaline-like surface
19 interposed with a fibrocartilage healing response between each graft.

20 This procedure is technically difficult, as all grafts must be taken with the axis of
21 the harvesting coring drill being kept perpendicular to the articular surface at the point of
22 harvest. Also, all graft placement sites must be drilled with the axis of a similar coring
23 tool being kept perpendicular to the articular surface at the point of implantation. Further,
24 all grafts must be placed so that the articular surface portion of these cartilage and bone
25 plugs is delivered to the implantation site and seated at the same level as the surrounding
26 articular surface. If these plugs are not properly placed in relation to the surrounding
27 articular surface, the procedure can have a very detrimental effect on the mating articular
28 surface. If the plugs are placed too far below the level of the surrounding articular
29 surface, no benefit from the procedure will be gained. Further, based on the requirement

1 of perpendicularity on all harvesting and placement sites, the procedure requires many
2 access and approach angles that typically require an open field surgical procedure.
3 Finally, this procedure requires a lengthy post-operative non-weight bearing course.

4 Transplantation of previously harvested hyaline cartilage cells from the same
5 patient has been utilized in recent years. After the cartilage is removed or harvested, it is
6 cultured in the lab to obtain an increase in the number of cells. These cells are later
7 injected back into the focal defect site and retained by sewing a patch of periosteal tissue
8 over the top of the defect to contain the cells while they heal and mature. The
9 disadvantages of this procedure are its enormous expense, technical complexity, and the
10 need for an open knee surgery. Further, this technique is still considered somewhat
11 experimental and long-term results are unknown. Some early studies have concluded that
12 this approach offers no significant improvement in outcomes over traditional abrasion
13 and microfracture techniques.

14 U.S. Patent No. 5,782,835 to Hart et al. discloses an apparatus and method for
15 repair of articular cartilage including a bone plug removal tool, and a bone plug
16 emplacement tool. The method of repairing defective articular cartilage includes the
17 steps of removing the defective cartilage and forming a hole of sufficient depth at the site.
18 A bone plug comprising intact bone and cartilage adhering thereto is removed from a
19 bone lacking defective cartilage is placed in the hole at the site of the damage.

20 U.S. Patent No. 5,413,608 to Keller discloses a knee joint endoprosthesis for
21 replacing the articular surfaces of the tibia comprising a bearing part which is anchored
22 on the bone having an upper bearing surface and a rotatable plateau secured on the
23 bearing surface and forming a part of the articular surface to be replaced. A journal rises
24 from the bearing surface and cooperates with a bore in the plateau to provide lateral
25 support.

26 U.S. Patent No. 5,632,745 to Schwartz describes a method of surgically
27 implanting into a site a bio-absorbable cartilage repair assembly. The assembly includes
28 a bio-absorbable polygonal T-shaped delivery unit having radial ribs to be mounted in the
29 removed area and a porous bio-absorbable insert supported by and in the delivery unit.

1 The method comprises the steps of preparing the site to receive the assembly by
2 removing a portion of the damaged cartilage and preparing the site to receive the
3 assembly by drilling and countersinking the bone. The assembly is inserted and seated
4 using an impactor in the drilled and countersunk hole in the bone until the assembly is
5 flush with the surrounding articular surface.

6 U.S. Patent No. 5,683,466 to Vitale illustrates an articular joint surface
7 replacement system having two opposing components. Each component has a tapered
8 head piece for covering the end of a bone and for acting as an articular surface, an
9 integrally formed screw stem of sufficient length to extend into the bone and inwardly
10 angled bone grips on the underside of the head piece to allow fixation to the bone by
11 compression fit. The partially spherical convex shaped exterior of the first component
12 complements the partially spherical concave shaped exterior of the second component.

13 U.S. Patent No. 5,702,401 to Shaffer discloses an intra-articular measuring device
14 including a hollow handle defining a first passageway and a hollow tube having a second
15 passageway extending from the handle, the hollow tube carrying a projection at its distal
16 end for seating on a fixed site and a probe disposed at the distal end of the hollow tube
17 which may be directed to a second site, to enable measurement of the distance between
18 the first and second sites.

19 U.S. Patent No. 5,771,310 to Vannah describes a method of mapping the three-
20 dimensional topography of the surface of an object by generating digital data points at a
21 plurality of sample points on said surface, each digital data point including a property
22 value and a position value corresponding to a particular point representing the properties
23 of the surface of the object. A 3-D transducer probe (e.g., a digitizer) is moved on or
24 over the surface along a random path, and the sample points are digitized to generate a
25 real-time topography or map on a computer screen of selected properties of the object,
26 including without limitation, surface elevation, indentation stiffness, elevation of sub-
27 surface layers and temperature.

28 Prosthetics for total knee replacement (TKR), whereby the entire knee joint or a
29 single compartment of the knee joint is replaced can be a common eventuality for the

1 patient with a large focal defect. Although these patients are also managed with anti-
2 inflammatory medications, eventual erosion of the remaining articular cartilage results in
3 effusion, pain, and loss of mobility and/or activity for the patient. Problems encountered
4 after implanting such prostheses are usually caused by the eventual loosening of the
5 prosthetic due to osteolysis, wear, or deterioration of the cements used to attach the
6 device to the host bones. Further, some prostheses used are actually much larger than the
7 degenerated tissue that needs to be replaced, so that extensive portions of healthy bone
8 are typically removed to accommodate the prostheses. Patients who undergo TKR often
9 face a long and difficult rehabilitation period, and the life span of the TKR is accepted to
10 be approximately 20 years. Accordingly, efforts are made to forgo the TKR procedure
11 for as long as possible.

12 Accordingly, there is a need for an improved joint surface replacement system
13 that would be effective in restoring a smooth and continuous articular surface and that
14 would also be as durable as the former hyaline cartilage surface, within the context of a
15 minimally invasive procedure that allows for a nearly immediate return to activity,
16 restoration of lifestyle, and pain relief.

17

SUMMARY OF THE INVENTION

1
2 The present invention provides tools and methods for mapping and measuring the
3 articular surface of a joint (or of any bony surface) and for fabricating a prosthetic device
4 based on this recorded data.

5 In one method consistent with the invention, once the defect of the chondral
6 surface has been identified, a guide pin is inserted arthroscopically. A fixation screw
7 having a tapered distal tip and an aggressive distal end thread form is then driven into the
8 subchondral bone in relation to a reference axis that is approximately central to the
9 defect. The fixation device also serves to define a tangent point to the surrounding
10 articular surface. The screw is driven by a socket type driver that engages a hex-shaped
11 proximal extension. A further cylindrical proximal extension of the screw (or other
12 mating feature, e.g., a recess in the screw) that eventually serves as a fixation element for
13 the surface prosthetic is at this time concealed with a cover (or other mating feature
14 corresponding to the mating feature of the screw, e.g., a plug for mating with a screw
15 having a recess as its mating feature) having a radiused proximal end. One or more
16 milled slots run the length of the uniform diameter portion of the screw.

17 Under arthroscopic view, the screw depth is adjusted so that the radiused cover
18 surface is positioned tangent to the radius that defines the existing articular surface. At
19 this time, the guide pin is removed and the knee is articulated. The depth positioning of
20 the radiused cover establishes an origin or reference point for all future measuring,
21 cutting, and prosthetic machining operations. Arthroscopic examination is carried out to
22 confirm positioning.

23 A measuring tool is inserted on the reference axis. A central element of the
24 measuring tool is a static post that establishes the axial location of origin. By rotating
25 the outer arm or outrigger of the measuring tool relative to the static post while also
26 maintaining contact with the articular surface, an axial displacement or Z dimension can
27 be established relative to the origin for any point along the known radial sweep of the
28 outrigger to determine the final geometry of the prosthetic surface which fits within the
29 defect. These Z dimensions can be recorded in real time with conventional dial gauge

1 indicators, or with digital recording devices, or by using marking techniques. Although
2 numerous points may be taken, ideally a minimum number of points are taken to
3 accurately define the target articular surface.

4 Locating surfaces or features created on the screw, (or alternatively, on the radius
5 cover, as described in alternative embodiments herein), correlate to some surface or
6 feature on the measuring tool and allow the measurement of the rotational position of the
7 points about the axis with respect to the locating surfaces. Data recorded during the
8 mapping procedure can then be entered into parametric engineering design software or
9 similar algorithm to define a three dimensional surface matched to the bearing surface
10 geometry to be implanted and reproduce the anatomic contours mapped.

11 An alternative measuring device for obtaining the articular surface dimension
12 includes an outer marking element and an inner recording element. The marking element
13 includes a sharp indenting mechanism which when pressed by the surgeon creates a
14 depression or mark in the relatively soft surface of the recording element, which deforms
15 at these marked points so that they can be utilized as patient data. The recording
16 element also includes a surface that corresponds to the surface of the proximal extension
17 of the fixation screw. During the mapping procedure, data points are established of the
18 rotational position of the mapped articular surface relative to the screw. These data
19 points are translated to the implant geometry so that the accurate rotational location of the
20 implant relative to the screw is maintained.

21 In order to secure the implant to the fixation screw, a precision taper (or other
22 component of a mating feature) is machined into a protrusion (or other component of a
23 mating feature) on the back of the device. The implant may be constructed of cobalt
24 chromium, or other materials. The implant may also include a slight outward taper or
25 protrusion along the diametrical surface to enhance load bearing or load transfer
26 properties of the implant to surrounding bone. Additionally, a series of radial cuts may
27 create surfaces that increase resistance of the implant to rotational forces. These features
28 may be located around the outer diameter of the implant.

1 In another aspect, the invention includes a compass instrument for measurement
2 and surface preparation of the implant target site subsequent sizing of the implant. This
3 compass instrument is configured so that it can be delivered to the site arthroscopically,
4 and when coupled to the axis defined by the guide pin it can be used for measuring and
5 cutting operations.

6 In another embodiment, the compass instrument consists of a handle, a cannulated
7 shaft that extends through the handle, and a cannulated distal offset arm configured to
8 serve as a linearly adjustable mounting tool for a series of cutting blades, boring blades,
9 or measuring probes.

10 With the guide pin advanced through the instrument shaft, when fitted with a
11 blade, a fixed length from the rotational or reference axis to the cutting blade's cutting
12 surface is established. This defines the radius that is effected as the instrument is rotated
13 around the guide pin, and corresponds to the overall diameter of the implant. This sharp
14 cutting blade is used to circumscribe and cleanly cut the surrounding articular cartilage.

15 In another aspect, the invention features a bone cutting or scoring instrument
16 whereby the bone-cutting instrument is positioned on the guide pin reference axis and is
17 used to prepare the target site to match in configuration and dimension the contacting
18 surface of the implant. The matching fit between the bone surfaces of the prepared
19 target site and the bone contacting surfaces of the implant can advantageously ensure
20 long term clinical results with the implant, as poor quality of fit between bone surfaces
21 and bone contacting surfaces of traditional orthopedic prosthetic devices has been noted
22 to contribute to early clinical failures.

23 Following fabrication of the implant, a second surgical procedure is performed.
24 The radiused cover is removed exposing a precision taper (or, alternatively, the cover
25 may be removed during the first procedure). A pin with a distally mounted element is
26 placed through the central lumen of the fixation screw so that the distally mounted
27 element is secured into the screw. This element carries one or more suture strands that
28 now trail from the fixation screw. The sutures are then threaded through the implant and
29 a knot or bead may be created proximal to the implant. By continuing to manipulate and

1 tension the suture strands, the implant can be brought coaxial to the fixation screw. Once
2 coaxial, the implant is aligned via engagement of the keyed elements and driven into
3 place with a plastic driving rod and mallet. Finally, through the guide aperture on the
4 surface of the implant, bone cement may be injected to enhance the contact surface
5 between the implant and the subchondral bone.

6 In another aspect, the invention further features a driver whereby the implant is
7 connected to the driver via a holder and a tether element, such as a suture or wire. The
8 implant and the driver are then inserted arthroscopically. Tension is then applied to the
9 tether element so that the implant is drawn back and seated on the driver. The implant
10 can then be controllably delivered to the prepared target site. The seat portion of the
11 driver may comprise a material that may be impacted to seat the implant without
12 damaging the implant surface.

13 In one aspect, a guide device for locating a guide pin or wire substantially normal
14 with respect to an articular surface of bone comprises a cannulated shaft having a distal
15 end and a central longitudinal axis; and a ring portion coupled to the distal end of the
16 shaft, the ring portion comprising a planar distal contact surface comprising a plurality of
17 points radially extending from any given point along the central longitudinal axis of the
18 shaft.

19 In another aspect, a guide device for locating a guide pin or wire substantially
20 normal with respect to an articular surface of bone having an anterior-posterior (AP)
21 curve and a medial-lateral (ML) curve comprises a cannulated outer shaft and a
22 cannulated inner shaft. The outer shaft has a central longitudinal axis and an outer
23 component at its distal end, the outer component comprising a set of arms, and the
24 cannulated inner shaft is slidably disposed within the cannula of the outer shaft, the inner
25 shaft having an inner component at its distal end and sharing the central longitudinal axis
26 of the outer shaft, the inner component comprising a set of arms.

27 In method form, a method for replacing a portion of an articular surface of bone
28 comprises defining an axis generally normal to the portion of an articular surface of bone
29 to be replaced; excising at least the portion to be replaced by cutting the articular surface

1 radially symmetrically about the axis, thereby creating an excised portion of the articular
2 surface; selecting an implant corresponding to the dimensions of the excised portion from
3 a set of variously-sized implants; and installing the selected implant into the excised
4 portion.

5 In method form, a method for replacing a portion of an articular surface of bone
6 having an anterior-posterior (AP) curve and a medial-lateral (ML) curve comprises
7 defining an axis generally normal to the portion of an articular surface of bone to be
8 replaced using an anterior-posterior (AP) curve and a medial-lateral (ML) curve of the
9 articular surface; excising at least the portion to be replaced by cutting the articular
10 surface radially symmetrically about the axis, thereby creating an excised portion of the
11 articular surface; selecting an implant corresponding to the dimensions of the excised
12 portion from a set of variously-sized implants; and installing the selected implant into the
13 excised portion.

14 In a further aspect, a tool for holding an implant comprises an activatable suction
15 source; and an elastomeric suction tip adapted to receive an implant, the tip being
16 coupled to the suction source.

17 In method form, a method for holding an implant comprises coupling a suction
18 source to an implant; and activating the suction source.

19 In method form, a method for delivering an implant comprises coupling a suction
20 source to an implant; activating the suction source; approximating the implant to its
21 delivery site; and applying a force to the implant in the direction of the delivery site.

22 In yet another aspect, a tool for removing an implant from its delivery site
23 comprises a cylindrical structure having a distal end; the distal end comprising a
24 longitudinal central axis, a circular blade portion having a leading edge comprising a
25 blade surface turned on the distal-most portion, and a lip portion disposed proximally
26 with respect to the leading edge; and a plurality of slits parallel to the longitudinal central
27 axis of the distal end formed along the length of the cylindrical structure, so as to permit
28 sufficient outward expansion of the distal end to accommodate the top edge of an implant
29 therein.

1 In method form, a method for removing an implant from its delivery site
2 comprises disposing the lip portion of the leading edge of the distal end of a removal tool
3 over the upper edge of an implant seated in its delivery site; and applying a pulling force
4 to the removal tool.

5 In still another aspect, a device for mapping a portion of an articular surface of
6 bone comprises a handpiece, an inner shaft, a contact tip, a rotary measuring element, and
7 a linear measuring element. The inner shaft runs along the length of and is disposed
8 within the handpiece and comprises a mating feature for mating with a fixed element
9 located substantially normal with respect to an articular surface. The contact tip is
10 slidably and rotatably disposed about the inner shaft. The rotary measuring element is
11 coupled to and rotating with the contact tip. The linear measuring element is nested
12 concentrically and coaxially to the rotary measuring element, and coupled to and moving
13 linearly with the contact tip.

14 A generic bone implant, or set of standardized implants, may further be created
15 based on using a guide device to develop an axis normal to an articular surface of bone
16 and collecting only one or two data points. A generic cutting tool may be used to cut the
17 bone to a point where a generic implant can be used. Several improved tools relating to
18 the procedure for using such an implant, as well as methods for using implants consistent
19 with the invention are further described hereinbelow, including: single-axis and biaxial
20 drill guide tools and methods, generic single-axis implant methods and devices, generic
21 biaxial implant methods and devices, tools and methods for holding or delivering an
22 implant, removal or revision tools and methods, digital measuring systems and methods,
23 and set of measuring gauges for determining the appropriate implant dimensions.

24

25 DESCRIPTION OF THE DRAWINGS

26 Figure 1 is a fragmentary side view of a knee having therein an exemplary
27 assembled fixation device and implant of the joint surface repair system surgically
28 implanted by the method in one embodiment of the present invention;

1 Figure 2a is an exploded side view of an exemplary fixation screw and hex-
2 shaped proximal extension in one embodiment of the present invention;

3 Figure 2b is an exploded perspective view of an exemplary fixation screw and
4 hex-shaped proximal extension in one embodiment of the present invention;

5 Figure 3a is a side view of an exemplary assembled fixation screw and hex shaped
6 extension in one embodiment of the present invention;

7 Figure 3b is an exploded perspective view of another exemplary fixation screw
8 and implant in one embodiment of the present invention;

9 Figure 4a is a perspective view of the upper surface of an exemplary implant in
10 one embodiment of the present invention;

11 Figure 4b is a side view of an exemplary implant in one embodiment of the
12 present invention;

13 Figure 4c is a perspective view of the lower surface of an exemplary implant in
14 one embodiment of the present invention;

15 Figure 5a is a side view of an exemplary assembled fixation device and implant in
16 one embodiment of the present invention;

17 Figure 5b is a perspective view of an assembled fixation device and implant in
18 one embodiment of the present invention;

19 Figure 5c is a perspective view of the upper surface of an exemplary implant, in
20 one embodiment of the present invention;

21 Figure 5d is a perspective view of the lower surface of an exemplary implant, in
22 one embodiment of the present invention;

23 Figure 6a is a sectional view of a knee having damaged articular cartilage,
24 showing an exemplary guide pin drilled into the central portion of the defect and an
25 arthroscope being disposed adjacent thereto, in a surgical procedure consistent with one
26 embodiment of the present invention;

27 Figure 6b is a side view of the distal tip of an exemplary drill device for boring a
28 pilot hole to receive an exemplary fixation screw, in one embodiment of the present
29 invention;

1 Figure 7a is a sectional view of a knee having damaged articular cartilage,
2 showing an exemplary fixation screw being driven into the defect by an exemplary socket
3 type driver arranged on the guide pin, in a surgical procedure consistent with one
4 embodiment of the present invention;

5 Figure 7b is a side view of the exemplary fixation screw, socket type driver and
6 guide pin of Figure 7a, illustrating the hex shaped proximal extension in a cross-sectional
7 view, in a surgical procedure consistent with one embodiment of the present invention;

8 Figure 8a is a perspective view of a knee having damaged articular cartilage,
9 showing an exemplary fixation screw and hex-shaped proximal extension implanted in
10 the defect after removal of an exemplary socket type driver and guide pin, in a surgical
11 procedure consistent with one embodiment of the present invention;

12 Figure 8b is a sagittal view of the exemplary fixation screw and hex-shaped
13 proximal extension of Figure 8a implanted in the defect after removal of an exemplary
14 socket type driver and guide pin, in a surgical procedure consistent with one embodiment
15 of the present invention;

16 Figure 8c is a perspective view of an exemplary fixation screw, proximal
17 extension and cover, in one embodiment of the present invention;

18 Figure 9a is a sectional view of an exemplary fixation screw and hex-shaped
19 proximal extension implanted in the defect with the exemplary guide pin replaced and an
20 exemplary measuring tool arranged thereon, in a surgical procedure consistent with one
21 embodiment of the present invention;

22 Figure 9b is a side partial cross-sectional view of the exemplary fixation screw
23 and hex-shaped proximal extension of Figure 9a implanted in the defect with the
24 exemplary guide pin replaced and an exemplary measuring tool arranged thereon, in a
25 surgical procedure consistent with one embodiment of the present invention;

26 Figure 9c is a perspective view of an exemplary fixation screw and proximal
27 extension, with the cover removed, in one embodiment of the present invention;

28 Figure 10a is a sectional view of an exemplary fixation screw and hex-shaped
29 proximal extension implanted in the defect, after removal of the hex-shaped proximal

1 extension, with an exemplary pin and suture strands placed therethrough, in a surgical
2 procedure consistent with one embodiment of the present invention;

3 Figure 10b is a side partial cross-sectional view of the exemplary fixation screw
4 and hex-shaped proximal extension of Figure 10a, implanted in the defect, with an
5 exemplary pin and suture strands placed therethrough, in a surgical procedure consistent
6 with one embodiment of the present invention;

7 Figure 11a is a sectional view of an exemplary fixation screw implanted in the
8 defect, with an exemplary pin and suture strands placed therethrough, showing the
9 implanted fixation screw with the implant being tensioned on the suture strands, in a
10 surgical procedure consistent with one embodiment of the present invention;

11 Figure 11b is a partial cross-sectional view of the exemplary fixation screw of
12 Figure 9a implanted in the defect, showing the implant positioned in the interchondular
13 notch, in a surgical procedure consistent with one embodiment of the present invention;

14 Figure 12 is a sectional view of an exemplary fixation screw implanted in the
15 defect, wherein, after placement of the implant and removal of the suture strands, the
16 implant is driven into place with an impactor and hammer, in a surgical procedure
17 consistent with one embodiment of the present invention;

18 Figure 13 is a side cross-sectional view of an exemplary fixation screw implanted
19 in the defect, after placement of the implant, wherein, after removal of the impactor and
20 hammer, cement is injected between the implant and the bone, in a surgical procedure
21 consistent with one embodiment of the present invention;

22 Figure 14a is a schematic representation of the two datum curves used to define a
23 patient-specific three-dimensional surface for construction of the articular or lower
24 surface of an implant in one embodiment of the present invention;

25 Figure 14b is a top view of an exemplary hex-shaped proximal extension in one
26 embodiment of the present invention;

27 Figure 14c is a perspective view of the bone-contacting or upper surface of an
28 exemplary implant, in one embodiment of the present invention;

1 Figure 15a is a perspective view of an exemplary compass instrument, in one
2 embodiment of the present invention;

3 Figure 15b is a perspective view of the distal offset arm of an exemplary compass
4 instrument and cutting blade to be mounted thereon, in one embodiment of the present
5 invention;

6 Figure 15c is a perspective view of an exemplary driver, showing an exemplary
7 implant on an exemplary tether element, in one embodiment of the present invention;

8 Figure 15d is a perspective view of an exemplary driver, showing an exemplary
9 implant tensioned on an exemplary tether element, in one embodiment of the present
10 invention;

11 Figure 16 is a perspective view of an exemplary compass instrument and cutting
12 blade mounted on an exemplary guide pin, in one embodiment of the present invention;

13 Figure 17a is a perspective view of another exemplary cutting blade, in one
14 embodiment of the present invention;

15 Figure 17b is a perspective view of an exemplary measuring probe, in one
16 embodiment of the present invention;

17 Figure 17c is a perspective view of an exemplary multi-faced blade mounted in
18 the distal offset arm of an exemplary compass instrument, in one embodiment of the
19 present invention;

20 Figure 18a is a perspective view of an exemplary site preparation and cutting
21 device, in one embodiment of the present invention;

22 Figure 18b is a cross sectional view of the exemplary site preparation and cutting
23 device of Figure 18a, in one embodiment of the present invention;

24 Figure 18c is a perspective view of another exemplary site preparation and cutting
25 device, in one embodiment of the present invention;

26 Figure 18d is a side view of another exemplary site preparation and cutting
27 device, in one embodiment of the present invention;

28 Figure 18e is a perspective view of another exemplary site preparation and cutting
29 device, in one embodiment of the present invention;

1 Figure 19a is a sectional view of the upper surface of an exemplary implant, in
2 one embodiment of the present invention;

3 Figure 19b is a side view of a portion of the exemplary implant of Figure 19a, in
4 one embodiment of the present invention;

5 Figure 19c is a perspective view of the upper surface of the exemplary implant of
6 Figure 19a, in one embodiment of the present invention;

7 Figure 19d is an exploded perspective view of another exemplary implant with
8 taper lock ring, washer and suture, in one embodiment of the present invention;

9 Figure 19e is a top perspective view of the exemplary implant of Figure 19d
10 seated in the taper lock ring, in one embodiment of the present invention;

11 Figure 19f is a bottom perspective view of the exemplary implant of Figure 19d
12 seated in the taper lock ring, with washer and suture, disposed within an incision near the
13 defect site, in one embodiment of the present invention;

14 Figure 19g is a perspective view of the exemplary implant of Figure 19d seated in
15 the taper lock ring, with washer and suture, wherein the suture is threaded through an
16 aperture at the distal end of a seating tool, at a first point in time during the process of
17 seating the implant into the defect site, in one embodiment of the present invention;

18 Figure 19h is another perspective view of the exemplary implant of Figure 19d
19 seated in the taper lock ring, with washer and suture, wherein the suture is threaded
20 through an aperture at the distal end of a seating tool, at a second point in time during the
21 process of seating the implant into the defect site, in one embodiment of the present
22 invention;

23 Figure 19i is another perspective view of the exemplary implant of Figure 19d
24 seated in the taper lock ring, wherein the distal end of a seating tool is disposed onto the
25 implant, at a third point in time during the process of seating the implant into the defect
26 site, in one embodiment of the present invention;

27 Figure 20a is a perspective view of an exemplary inner recording element of an
28 exemplary measuring device, in one embodiment of the present invention;

1 Figure 20b is a perspective view of an exemplary outer marking element of an
2 exemplary measuring device, in one embodiment of the present invention;

3 Figure 20c is a cross-sectional perspective view of an exemplary measuring
4 device showing an exemplary inner recording element and an exemplary outer marking
5 element, in one embodiment of the present invention;

6 Figure 20d is an exploded perspective view of another exemplary measuring
7 device, in one embodiment of the present invention;

8 Figure 20e is a perspective view of the exemplary measuring device of Figure
9 20d, illustrating an exemplary scroll alignment feature, in one embodiment of the present
10 invention;

11 Figures 20f and 20g are side views of the exemplary measuring device of Figure
12 20d illustrating the translational motion of the handle with respect to the tip of the device,
13 in one embodiment of the present invention;

14 Figure 20h is a perspective view of the distal end of the exemplary measuring
15 device of Figure 20d, in one embodiment of the present invention;

16 Figure 20i is a perspective view of the distal end of the exemplary measuring
17 device of Figure 20d with outer element, disposed upon the inner element engaging a
18 mating feature of the screw, in one embodiment of the present invention;

19 Figure 21 is a perspective view of an exemplary unitary implant, in one
20 embodiment of the present invention;

21 Figure 22 is a perspective view of a defect site with a keyed aperture for receiving
22 the exemplary unitary implant of Figure 21, in one embodiment of the present invention;

23 Figure 23 is a perspective view of an exemplary composite implant, in one
24 embodiment of the present invention;

25 Figure 24 is a perspective view of another exemplary composite implant, in one
26 embodiment of the present invention;

27 Figure 25 is a perspective view of an exemplary implant illustrating the geometry
28 of said implant for use in an algorithm for establishing minimum implant thickness, in
29 one embodiment of the invention;

1 Figure 26 is a perspective view of an exemplary implant illustrating the geometry
2 of said implant for use in an algorithm for establishing minimum implant thickness, in
3 one embodiment of the invention;

4 Figure 27a is a perspective view of an exemplary drill guide device in an
5 exemplary generic bone implant embodiment of the present invention;

6 Figure 27b is a perspective view of another exemplary drill guide device in an
7 exemplary generic bone implant embodiment of the present invention;

8 Figure 28a is a top sectional view of the anterior-posterior plane of an articulating
9 surface in an exemplary generic bone implant embodiment of the present invention;

10 Figure 28b is a side sectional view of the medial-lateral plane of an articulating
11 surface in an exemplary generic bone implant embodiment of the present invention;

12 Figure 29 is a perspective view of the use of an exemplary drill guide in an
13 exemplary generic bone implant embodiment of the present invention, as the drill guide is
14 brought up to a lesion site of the articulating surface;

15 Figure 30 is a perspective view of the use of an exemplary drill guide in an
16 exemplary generic bone implant embodiment of the present invention, as the drill guide is
17 seated into position and a guide pin is driven through the drill guide;

18 Figure 31 is a perspective view of the articulating surface in an exemplary generic
19 bone implant embodiment of the present invention, as a bone drill is passed over the
20 guide pin to create a pilot hole for the screw;

21 Figure 32 is a cross-sectional view of the articulating surface in an exemplary
22 generic bone implant embodiment of the present invention, as the screw is driven into the
23 pilot hole with a cap positioned into the screw;

24 Figure 33 is a cross-sectional view of the articulating surface in an exemplary
25 generic bone implant embodiment of the present invention, as the cap is removed and a
26 rod is inserted into the screw, and the guide is positioned back over the rod and returned
27 to its position in contact with the articular surface;

1 Figure 34 is a side perspective view of the articulating surface in an exemplary
2 generic bone implant embodiment of the present invention, as the guide is used to take a
3 depth measurement needed for implant geometry;

4 Figure 35 is a top perspective view of the lower surface of an exemplary implant
5 in an exemplary generic bone implant embodiment of the present invention;

6 Figure 36 is a side perspective view of an exemplary implant in an exemplary
7 generic bone implant embodiment of the present invention;

8 Figure 37 is a side perspective view of another exemplary implant in an
9 exemplary generic bone implant embodiment of the present invention;

10 Figure 38 is a perspective view of the articulating surface in an exemplary generic
11 bone implant embodiment of the present invention, as the implant site is reamed with a
12 cutting/reaming tool in preparation for receiving an implant;

13 Figure 39 is a top perspective view of an alternative exemplary cutting/reaming
14 tool in an exemplary generic bone implant embodiment of the present invention,

15 Figure 40 is a side perspective view of an exemplary cleaning tool for cleaning
16 the female taper of the screw prior to delivery of the implant, in an exemplary generic
17 bone implant embodiment of the present invention;

18 Figure 41 is a side perspective view of an exemplary suction tool for holding and
19 delivering the implant, in an exemplary generic bone implant embodiment of the present
20 invention;

21 Figure 42 is a side perspective view of an exemplary suction tool holding an
22 implant in place, in an exemplary generic bone implant embodiment of the present
23 invention;

24 Figure 43 is a side cross-sectional view of an exemplary suction tool holding an
25 implant in place, with an implant in place, in an exemplary generic bone implant
26 embodiment of the present invention;

27 Figure 44 is a top perspective view of the articulating surface in an exemplary
28 generic bone implant embodiment of the present invention, with the implant driven into
29 its final position;

1 Figure 45 is a side perspective view of an exemplary removal/revision tool in an
2 exemplary generic bone implant embodiment of the present invention;

3 Figure 46 is a side perspective view of an exemplary removal/revision tool, with
4 an implant in place, in an exemplary generic bone implant embodiment of the present
5 invention;

6 Figure 47 illustrates an exemplary alternatively-keyed embodiment of the screw
7 and the exemplary alternatively-keyed implant to which it is adapted to mate, in an
8 exemplary embodiment of the present invention;

9 Figure 48 illustrates a side cross-sectional view of an exemplary alternatively-
10 keyed embodiment of the screw, in an exemplary embodiment of the present invention;

11 Figure 49 illustrates a side perspective view of the articular surface of a lesion site
12 and an exemplary biaxial measuring tool for developing an axis normal to the articular
13 surface, in one embodiment of the present invention

14 Figure 50 illustrates another side perspective view of the articular surface of a
15 lesion site and an exemplary biaxial measuring tool for developing an axis normal to the
16 articular surface, in one embodiment of the present invention;

17 Figure 51 illustrates a side exploded view of an exemplary biaxial measuring tool,
18 in one embodiment of the present invention;

19 Figure 52 illustrates a top perspective view of the distal end of an exemplary
20 biaxial measuring tool in a first position, in one embodiment of the present invention;

21 Figure 53 illustrates a top perspective view of the distal end of an exemplary
22 biaxial measuring tool in a second position, in one embodiment of the present invention;

23 Figure 54 illustrates an exemplary digital measuring system in one embodiment of
24 the present invention;

25 Figure 55 illustrates an exploded perspective view of an exemplary handpiece in
26 an exemplary digital measuring system in one embodiment of the present invention;

27 Figure 55a illustrates a top perspective cutaway view of an exemplary printed
28 linear index strip passing through an exemplary linear head for reading, in an exemplary

1 handpiece in an exemplary digital measuring system in one embodiment of the present
2 invention;

3 Figure 55b illustrates a top perspective cutaway view of an exemplary printed
4 rotary index strip passing through an exemplary rotary head for reading, in an exemplary
5 handpiece in an exemplary digital measuring system in one embodiment of the present
6 invention;

7 Figure 55c illustrates an exemplary linear index strip in an exemplary handpiece
8 in an exemplary digital measuring system in one embodiment of the present invention;

9 Figure 55d illustrates an exemplary rotary index strip in an exemplary handpiece
10 in an exemplary digital measuring system in one embodiment of the present invention;

11 Figure 56a illustrates a side perspective view of an exemplary handpiece with the
12 probe assembly removed, in an exemplary digital measuring system in one embodiment
13 of the present invention;

14 Figure 56b illustrates a side perspective view of an exemplary handpiece,
15 including the probe assembly, in an exemplary digital measuring system in one
16 embodiment of the present invention;

17 Figure 57 illustrates a top perspective view of an assembled exemplary handpiece,
18 in an exemplary digital measuring system in one embodiment of the present invention;

19 Figure 58 illustrates a side perspective view of an assembled exemplary
20 handpiece, in an exemplary digital measuring system in one embodiment of the present
21 invention;

22 Figure 59 illustrates a top cross-sectional view of an assembled exemplary
23 handpiece, in an exemplary digital measuring system in one embodiment of the present
24 invention;

25 Figure 60 illustrates a side cross-sectional view of an assembled exemplary
26 handpiece, in an exemplary digital measuring system in one embodiment of the present
27 invention; and

28 Figure 61 illustrates a side cutaway perspective view of an exemplary base unit, in
29 an exemplary digital measuring system in one embodiment of the present invention.

DETAILED DESCRIPTION OF THE EMBODIMENTS

As an overview, Figure 1 shows a surgically implanted articular joint surface repair system consistent with the present invention. As shown, the assembled fixation device includes fixation screw 10, implant 40, and anchoring pin 5, implanted in the defect in the medial femoral chondral surface 55 of knee 50. Implant 40 is configured so that bearing or bottom surface 41 of the implant reproduces the anatomic contours of the surrounding articular surface of the knee 50.

As illustrated in Figures 2a, 2b and 3a, fixation screw 10 comprises threads 12 running the length of the screw from tapered distal tip 11 to hex-shaped drive 15. In the embodiment shown, the screw includes a tapered distal end 11, and aggressive distal threads 12, so that, as screw 10 is driven into the subchondral bone 100 (as shown in Figure 7a) the screw dilates open and radially compress the subchondral bone, increasing its local density and thereby increasing the fixation strength of the screw. The screw 10 may taper down to the distal end 11, and the diameter of the screw may become greater and more uniform at the center thereof, so that adjustment of the depth of the screw 10 with respect to the subchondral bone 100 does not significantly further increase or decrease the compression of the subchondral bone.

One or more milled slots 13 run the length of the uniform diameter portion of the screw 10. Slots 13 ensure that as healing or tissue in-growth begins, migrational or rotational movement of the screw is inhibited. The screw 10 is configured to be driven by a female or socket type driver 2 as shown in Fig. 7b, which engages a hex-shaped drive 15 located toward the proximal end 17 of the screw. A cylindrical proximal extension 14 (which may, alternatively, be a recess 303 which mates with a plug or other protrusion on the implant surface, as shown in Figure 8c) extends from hex-shaped drive 15, which eventually serves as a fixation element for surface prosthetic implant 40. Through hole 16 runs through the central axis of the screw. Hex-shaped cover 30 (which may, alternatively, be a plug 301, for mating with a fixation element 302 having a recess, as shown, e.g., in Figures 3b, 8c, and 9c, and described in the following paragraph) is configured to engage the cylindrical proximal extension 14 of the screw 10 to prevent

1 exposure of the cylindrical extension from inadvertent contact or damage. The hex-
2 shaped cover 30 is finished with a radiused proximal end 31 that assists in the visual
3 determination of the correct depth setting of the screw. Through hole 32 in the hex-
4 shaped cover 30 corresponds with through hole 16 in the fixation screw 10.

5 Alternatively, as shown in Figures 3b, 8c, and 9c, the female-shaped cover may
6 instead be a plug 301 having a male-shaped mating component 305, for mating with a
7 fixation element 302 of a screw 10' having a recess 303. Additionally, the shape of the
8 cover and plug, or other recessed, protruding, or mating components may be other than
9 hexagonal, and those in the art will recognize that one of any number of shapes or
10 configurations for such components may be employed in a device or method consistent
11 with the invention.

12 Also, while many of the components described herein are cannulated, having
13 guide apertures, through holes, and/or central lumina along their length, for disposing
14 such components about a guide rod for proper location of the components with respect to
15 the articular surface, it should be recognized that a suture 313 or other flexible element,
16 or other guide feature may be used in place of a guide rod, or a guide rod or wire may be
17 eliminated altogether from one or more steps consistent with the invention described
18 herein. As shown in Figure 8c, the suture 313 may be fixedly or removably attached to
19 the plug 301.

20 As shown in Figures 4a, 4b and 4c, implant 40 comprises lower bearing surface
21 41, top surface 42 and protrusion 45 located centrally on the bottom surface. As the top
22 surface 42 of the implant 40 is not a bearing surface, and instead is fixed into subchondral
23 bone 100, a series of stepped machine cuts 43 following the contours of the defect are
24 created. By creating stepped machine cuts 43 a contoured contact surface matching the
25 defect in the subchondral bone 100 is created. This contact surface results in an increased
26 surface area that should enhance resistance to loosening of the implant 40 via rotational
27 or translational loading. In the illustrated embodiment, the stepped cuts are shown as
28 square cross-section cuts, but the cuts may be circular, triangular, or another
29 configuration.

1 In order to secure the implant 40 to the fixation screw 10, precision taper 44 is
2 machined into or onto a protrusion 45 on the top surface 42 of the implant. The
3 precision taper 44 is configured to engage the cylindrical proximal extension 14 of the
4 screw 10, once the hex-shaped cover 30 has been removed therefrom. Taper 44 may be
5 mated with extension 14 so that a friction fit is provided between these surfaces. The
6 assembled fixation device is shown in Figures 5a and 5b. Alternatively, other
7 engagement mechanisms such as snap-fits, press-fits, threads, or coupling elements, for
8 example, may also be used. In one embodiment, leading pin 47 arranged on the
9 protrusion 45 assists penetration into subchondral bone. Also, in one embodiment, guide
10 aperture 46 passes through the top 42 and bottom 41 surfaces of the implant 40, just
11 slightly off center of the reference axis 20A. Alternatively, guide aperture 46 may be
12 located in the center of the implant 40 and corresponds to through hole 16 running
13 through the central lumen in the fixation screw 10. Bone cement may be injected
14 through guide aperture 46 on the surface of the implant 40 and through hole 16 in the
15 fixation screw 10, to enhance the contact surface between the device and the subchondral
16 bone. In one embodiment, the implant is constructed of cobalt chromium, although other
17 materials may be used, including implantable plastics. Additionally, biologically active
18 coatings or surface treatments (e.g., to enhance bone ingrowth or improve wear
19 properties) may be utilized or combined as laminates, particularly with respect to the
20 bearing surfaces and bone contacting surfaces. Further exemplary materials that may be
21 used in fabricating an implant consistent with the invention are described hereinbelow.

22 As shown in Figure 3b, it is noted that precision taper 44 may be a male-shaped
23 component 304 instead of the above-described female component 44. In this
24 configuration, the male-shaped component 304 of the implant 40' is configured for
25 mating with a fixation element 302 of the screw 10' having a recess 303 adapted to
26 receive the male-shaped component 304.

27 By way of example, Figures 6a-13 depict one exemplary joint surface
28 methodology of the present invention. Figure 6a shows a focal defect 1 of the articular
29 surface 55 of the femoral chondyle bone of the knee 50. This defect is identified by

1 arthroscope 25 inserted in the area of the defect 1 during a diagnostic arthroscopy or
2 surgical arthroscopy. The disclosed surgical intervention begins by drilling a guide pin
3 20 defining reference axis 20A into the central portion of the defect 1 via an incision 200
4 typical of arthroscopic procedures. Placement of this pin may be done using visual,
5 freehand techniques, or may be located centrally by using outer element 71 of a
6 measuring tool 70 (as shown in Figures 9a and 9b), or other aiming device or technique,
7 to define a center. This reference axis 20A serves to establish a working axis located
8 central to the defect 1 for the procedures that follow, and arthroscope 25 may be used to
9 view the joint for purposes of establishing a reference axis 20A generally perpendicular
10 to and bisecting the existing articular surface 55 defined by radii 60 and 61, as shown in
11 Figure 8b. Referring to Figure 7a, 7b, 8a and 8b, fixation screw 10 and hex-shaped cover
12 30 are driven into the defect 1 in the subchondral bone 100 by socket-type driver 2
13 mounted over (i.e., about) guide pin 20 located on reference axis 20A. Under
14 arthroscopic view, the depth of fixation screw 10 may be adjusted by driver 2 so that the
15 bottom of the radiused surface 31 of the hex-shaped cover 30 is positioned tangent to the
16 radii 60 and 61 that define the existing articular surface 55. The guide pin 20 is removed
17 and the knee 50 is articulated through its range of motion to ensure that the height of the
18 radiused surface 31 of the hex-shaped cover 30 is proper, since the prosthetic surface 41
19 of the implant 40 is created also to be tangent to this radiused surface 31. The depth
20 positioning of the radiused surface 31 of the hex-shaped cover 30 establishes a point of
21 origin or a reference point for all future measuring and machining operations.

22 Arthroscopic examination may be carried out from multiple arthroscopic views to
23 confirm positioning.

24 A drill mechanism 306, as illustrated in Figure 6b, may be used to bore a pilot
25 hole for receiving a fixation screw 10 (as shown, e.g., in Figures 2a, 2b and 3a). As
26 shown, the drill may have a shank portion 307 and a bit portion 308. The bit portion 308
27 may include a spiral or parabolic fluted tip 309 having proximal 310, medial 311, and
28 distal 312 portions. The root diameter at the medial portion 311 is substantially equal to
29 the diameter of the fixation screw 10, and the diameter decreases as the distal portion 312

1 tapers away from the shank 307. The proximal portion 310 of the bit 308 may be used as
2 a visual indicator during drilling, to determine the point at which the proper bore depth
3 has been attained. The drill mechanism may have a central lumen (not shown) having a
4 diameter slightly greater than the diameter of the guide pin 20 (as illustrated in Figure 6a)
5 running along its length, so that, with the guide pin 20 in place, the drill 306 may be
6 disposed about the guide pin 20 during drilling to ensure proper location of the pilot hole
7 with respect to the articular surface 55. Alternatively, a self-drilling or self-tapping
8 screw, may be used, as those skilled in the art will recognize.

9 For surface preparation and accurate measurement of the implant site and the
10 subsequent sizing of the implant, instrument 120 is provided. The compass instrument
11 120 may be configured to serve as a mounting tool for a number of functional blades or
12 tips and when located about the axis 20A, via guide rod 20, may be used for measuring
13 and cutting operations. In the embodiment shown in Figure 15a, compass instrument 120
14 includes handle 110, a cannulated shaft 111 that extends through the handle, and a
15 cannulated distal offset arm 112. The instrument may be rigid in construction and may
16 be a durable reusable and resterilizable instrument. The distal offset arm 112 is
17 configured so that it can be introduced into a site through an incision 200 typical of an
18 arthroscopic procedure. Once the distal offset arm 112 has fully penetrated the incision
19 and enters the site, shaft 111 can be angularly repositioned so that it becomes more
20 coaxial to the reference axis 20A and advanced in-line with the reference axis 20A
21 towards the implant target site. While performing this maneuver to position the
22 compass instrument 120, the guide pin 20 should be removed from its position in the
23 defect 1. When compass 120 is in its proper position at or near the implant target site, the
24 guide pin 20 is delivered through the instrument cannulation 113, re-establishing the
25 working (reference) axis 20A used to define the implant geometry.

26 Referring to Figure 15b, within offset arm 112 is a slotted surface 114 for
27 engaging a series of cutting blades 121, boring blades 124, or measuring probes 122. The
28 slots 115 are configured so that said series of cutting blades 121, boring blades 124
29 (Figure 17c), measuring probes 122, 123 (Figures 17a, 17b), or like elements may be

1 partially constrained or fixed in position such that they may be adjusted linearly along the
2 length of the slotted surface 114 over a defined distance of travel. Intersecting the plane
3 of travel defined by slotted surface 114 and slots 115, is the cannulation 113.

4 As illustrated in Figure 16, when fitted with a cutting blade 121, and with the
5 guide pin 20 advanced through the shaft 113 of instrument 120, so that the guide pin
6 passes through a closely sized hole 116 in the cutting blade, the blade's position becomes
7 fully constrained. When constrained in this fashion, a fixed length from the rotational or
8 reference axis 20A to the cutting surface 117 of cutting blade 121 is established. This
9 defines the radius that is effected as the instrument 120 is rotated around the guide pin 20,
10 and corresponds to the overall diameter of the implant 40 that is delivered to the fully
11 prepared site. The cutting blade 121 is used to circumscribe and cleanly cut the
12 surrounding articular cartilage.

13 In an alternative embodiment, as shown in Figures, 17a and 17b, blade 123 and
14 measuring probe 122, respectively, may have multiple holes 118 that defines that
15 probe/blade's functional diameter. In addition, the blades may be specifically configured
16 so that staged or sequential cuts of varying depths and diameters can be performed within
17 the procedure. Also, such a blade can be configured by providing a readable scale 119
18 corresponding to the hole 118 pattern, so that the surgeon may determine and set the
19 appropriate diameter as needed by positioning the guide pin 20 in the corresponding hole.
20 As the readable scale 119 may be located on the blade 123 with respect to the blade's
21 cutting surface 117, a high degree of positional accuracy may be achieved as the scale
22 may be defined specifically for each type of blade. This approach creates an inexpensive
23 means of providing sharp blades of varying diameters and varying blade types without a
24 large inventory of size- and type-specific blades. Referring to Figure 17b, rounded tip
25 109 of measuring probe 122 can be used to determine the appropriate diameter and can
26 be similarly sized and secured in the compass instrument 120. The tip 109 may be
27 rounded to prevent marring of the articular surface. Figure 17c shows a boring bit or
28 bone cutting blade 124 with multiple cutting surfaces 107 and 108 configured in this
29 fashion.

1 Turning now to Figures 9a and 9b, with the guide pin 20 replaced, a measuring
2 tool 70 is inserted so that the reference axis 20A is utilized. A central element of the
3 measuring tool 70 is a post 75 that is static, establishes the axial location of the point of
4 origin 80, and mates with a rotational location feature within the screw 14. By rotating
5 the outer arm or outrigger 71 of the measuring tool 70 relative to the static post 75 while
6 also maintaining contact with the articular surface 55, an axial displacement or Z
7 dimension can be established relative to the point of origin 80 for any point along the
8 sweep of the outrigger. Each such Z dimension may be recorded in real time with
9 conventional dial gauge indicators 72 or with a digital recording device, such as disclosed
10 in U.S. Patent No. 5,771,310 to Vannah, or by using other known marking techniques.
11 Although numerous points may be taken, ideally a minimum number of points are taken
12 to define accurately the target articular surface. In other embodiments, multiple
13 outriggers that embody different diameters or an adjustable outrigger may be used to map
14 larger defects, and also to determine the final diameter of the prosthetic surface that fits
15 within the defect. It is noted that the measuring tool may comprise a spring or other
16 tensioning device (not shown), for urging the outrigger distally with respect to the handle
17 of the tool. In this aspect, the outrigger is manually pressed against the articular cartilage,
18 so as to maximally compress the articular cartilage upon recording data points, so that the
19 data points taken are of a maximally "loaded" or "compressed" dimension.

20 Figures 20a, 20b and 20c show an alternative measuring and mapping device 210
21 for obtaining the articular surface dimension, comprising housing 217 and a recording
22 element 218. As shown in Figure 20a, recording element 218 includes upper portion 219,
23 flange 222 and calibrated lower portion 220. Key-shaped surface 221 located at distal
24 end 225 of recording element 218 is configured to engage a reciprocal key-shaped
25 surface in the proximal extension 14 of fixation screw 10, or, for example, a key shaped
26 cover arranged on the proximal end of the screw (not shown). The upper portion 219 of
27 recording element 218 may be constructed of a relatively soft or other deformable
28 material that can be marked with patient data. Cannulated shaft 223 runs through the
29 central lumen of the recording element 218. As shown in Figure 20b, housing 217

1 includes a marking mechanism 224 located on the upper portion 226 of the housing, at or
2 within window or aperture 230. An indexing indicator 228 is located on the lower
3 portion 227 of the housing 217, at window or opening 229.

4 Turning to Figure 20c, recording element 218 is inserted in housing 217 of
5 measuring and mapping device 210, so that the distal end 225 of recording element 218
6 appears through opening 232. Tensioning means (not shown) in the device 210, enables
7 recording element 218 to move longitudinally within housing 218. With the guide pin 20
8 replaced, the measuring device 210 is inserted on the guide pin on reference axis 20A so
9 that key-shaped surface 221 engages the corresponding keyed surface of the screw and is
10 maintained in static position thereby. These key-shaped surfaces establish the rotational
11 position of the articular surface points to be mapped relative to the screw. During the
12 measuring and mapping procedure, the surgeon rotates housing 217 and outer arm or
13 outrigger 231 located at the distal end 235 of housing. By depressing marking
14 mechanism 224, a series of depressions or marked points 240 is established in the
15 relatively soft surface of the upper portion 219 of the recording element 218, which
16 deforms at these marked points so that they can be utilized as patient data. Indexing
17 indicator 228 and calibrated lower portion 220 of recording element 217 allow for
18 controlled rotational movement between housing 217 and recording element 218. In
19 this way, the rotational position of the mapped articular surface points 235 relative to the
20 screw 10 as appreciated by outer arm of outrigger 231, is translated to the implant
21 geometry as a feature so that the accurate rotational location of the implant 40 relative to
22 the screw 10 is maintained.

23 For example, as shown in Figures 8b and 9b, to accurately reproduce the two radii
24 60 and 61 that locally define the articular surface 55, four points, 81a and 81b, and 82a
25 and 82b, and the point of origin 80 are recorded. As any three points in a single plane
26 define a curve, by recording points 81a and 81b and the point of origin 80, radius 60
27 defining the medial-lateral aspect 68 of the chondyle can be determined. By recording
28 points 82a and 82b and the point of origin 80, the radius 61 defining the anterior-posterior
29 aspect 69 of the chondyle can be determined. In the example provided, in order to

1 maintain the relationship between these two defined radii, 60 and 61, the measuring tool
2 70 is constructed so that it can be accurately indexed from a fixed starting point along 90
3 degree intervals to capture or map said four points 81a, 81b, 82a and 82b, over the course
4 of its revolution.

5 Locating surfaces or features created on the radius cover 30, or along some length
6 of the fixation screw 10, hex-shaped drive surface of the screw 14 or on the cylindrical
7 proximal extension (or recess) of the screw 14, correlate to some surface or feature on the
8 measuring tool 70 and allow the measurement of the rotational position of the four
9 measured points 81a, 81b, 82 and 82b, about the reference axis 20A with respect to said
10 locating surfaces. This data becomes important in configuring the implant 40 with respect
11 to the fixation screw 10 so that the proper orientation of said measured points to
12 fabricated geometry is maintained. Of course, such measuring tool can be configured to
13 measure any number of points at any interval desired.

14 While the measurements are illustrated in Figures 9a and 9b as being taken from
15 the bottom of the radiused surface 31 of the hex-shaped cover 30 of the screw, the
16 measurements may alternatively be taken from the top of the screw 10' itself, as shown in
17 Figure 9c. As shown, in this embodiment, a key 315 or other alignment feature may be
18 provided, to indicate the starting point for taking measurements. In this configuration,
19 the measuring tool used, as well as the implant manufactured, both have a mating feature
20 matching the key 315, for properly locating the starting point of the measurements taken
21 and thereby subsequently properly aligning the implant with respect to the defect.

22 Other embodiments of measuring and recording tools are possible. One such
23 embodiment of a measuring and recording tool 210' is shown in Figures 20d – 20i. As
24 shown, measuring tool 210' comprises a handle 316, outer shaft 333, inner shaft 330,
25 scroll 317, a tactile feedback portion 318, ring 320 having a button 321 in communication
26 with a sharp marking point 326 thereunder, a rotating portion 322 having a rotational lock
27 323 which prevents rotation of the rotating portion 322 when engaged, and an outrigger
28 portion 324. The handle 316 remains fixed during rotation and does not move while the
29 tool 210' is used for measuring. Instead, the rotating portion 322 is rotated to a start

1 position and the rotational lock is engaged, securing the rotating portion 322 to the tactile
2 feedback portion 318 and thereby preventing its rotation. The scroll 317 is configured
3 with a notch 325 or similar mating feature to align with a corresponding mating feature
4 (not shown) of the handle 316, such that the scroll can only align at one rotational point,
5 at 0 degrees, with respect to the handle 316 upon loading into the tool 210', e.g., by
6 "snapping" into place. The sharp marking point 326 located inside the ring 320 under the
7 sharp marking point 326, marks a point of depression into the scroll 317 while first button
8 321 is being depressed. Instead of marking by making depressions on a scroll or spool,
9 marking could alternatively be made upon nearly any surface, e.g., using ink to record on
10 a paper spool, or by digital means.

11 As shown in Figures 20f and 20g, outer shaft 333, which is fixedly coupled to
12 rotating portion 322, outrigger 324 and ring 320, is freely rotatably disposed about inner
13 shaft 330 and slidably disposed about inner shaft 330 within a range bounded by points
14 334 and 337. In Figure 20f, the outrigger 324 is retracted, and outer shaft 333 is located
15 at a position of origin along a z-axis parallel to the inner 330 and outer 333 shafts, such
16 that the proximal end of the ring 320 is located at position 335. In Figure 20g, the
17 outrigger 324 is extended, and outer shaft 333 is located at a position .250 in. (.64 cm.)
18 from the origin of the z-axis parallel to the inner 330 and outer 333 shafts, such that the
19 proximal end of the ring 320 is located at position 335'. The motion of the sliding of the
20 outer shaft 333 about inner shaft 330 during marking is translated via the outer shaft 333,
21 rotating portion 322 and ring 320 (including marking button 321 and marking point 326)
22 to a location along the scroll 317. Thus, as the user rotates outrigger 324 by rotation of
23 rotating portion 322, the outrigger moves along the articular surface proximally or
24 distally with respect to the inner shaft, and the displacement of the outrigger 324 along a
25 z-axis parallel to the inner 330 and outer 333 shafts may be marked on the scroll 317 by
26 depression of the button 323 at various points along the rotation of the outrigger 324.
27 The tactile feedback portion 318 has a series of depressions 319 or other tactile feedback
28 means, e.g. spring ball plungers which engage in indentations (not shown) in the inner
29 shaft 330, spaced at 90 degrees from one another, so that when the rotational lock 323 is

1 engaged as rotating portion 322 is being rotated, the user feels a “click” or other tactile
2 feedback to indicate to the user the rotational location of the rotating portion 322 at 90
3 degree intervals with respect to the handle 316, i.e., at 90 degrees, 180 degrees, 270
4 degrees, and 0 (or 360) degrees, for purposes of marking at those points. It is further
5 noted that the starting point for marking may or may not be selected independent of the
6 90-degree rotational points, and that the rotating portion 322 may or may not be
7 configured so that it is not tied to the 90-degree indexing until the scroll lock 323 is
8 engaged.

9 As shown in Figures 20e, 20h and 20i, a keyed mating feature 331 may be
10 disposed at the distal end of the inner shaft 330 with respect to the outrigger portion, for
11 mating with a key feature 315 on the screw 10' (as shown in Figures 9c and 20i), so as to
12 locate properly the starting point of the measurements taken with respect to the screw,
13 and the scroll 317. Figure 20h illustrates a more detailed view of the distal end of the
14 marking tool 210', with outer shaft 333, inner shaft 330 with keyed mating feature 331,
15 and outrigger 324 with rounded end 338, which travels along the path of circle 339.
16 Figure 20i illustrates the measuring tool 210', with the keyed mating feature 331 inserted
17 into the recessed portion 303 of the screw 10' at its fixation element 302.

18 Referring now to Figure 14a, data recorded during the mapping procedure
19 described above can then be entered into a known parametric engineering design software
20 or similar algorithm, as four values, 85a, 85b, 85c, and 85d, corresponding to the four
21 measured points, 81a, 81b, 82a and 82b, with the origin 80 defining a reference plane.
22 These four values 85a, 85b, 85c and 85d, are represented by line elements that are
23 geometrically constrained to lie upon a circle 90, which represents the diameter of the
24 measuring tool 70. These line elements are also constrained to lie within planes that are
25 perpendicular to one another. Of course, more than four points may be taken and used to
26 map the articular surface, e.g., 8 points; however, a minimum of four points should be
27 taken, so that two intersecting datum curves may be defined for purposes of mapping.

28 Datum curves 86 and 87, representing the medial-lateral (“ML”) and anterior-
29 posterior (“AP”) curves, are constructed by connecting the end points of the line elements

1 81a and 81b, and 82a and 82b and the point of origin 80, which is common to both
2 curves. These two datum curves 86 and 87 can be used to construct the articular or
3 bottom surface 41 of the prosthetic implant 40. By sweeping datum curve 87 along a
4 path defined by datum curve 86, a three dimensional surface is now defined.

5 By constructing this series of geometric relationships in a known parametric
6 engineering model, patient-specific geometry can be input as values and the model
7 algorithm can be run to reproduce the anatomic contours mapped in the patients within
8 only a few moments. As a process, this generic model is the starting point for all patient
9 treatments. Sterile pins, screws, and measuring devices that are all non-patient-specific
10 may be stocked in the hospital and ready to use whenever an appropriate defect is
11 diagnosed. Patient-specific data may be transmitted from the surgeon to the fabricating
12 facility via an interface to the Internet or other network. Data input into the interface may
13 be read directly into the generic parametric model to produce a viewable and even
14 mappable patient-specific parametric model within moments. Confirmation by the
15 surgeon could initiate a work order for the production of the patient specific device.
16 Existing technology allows the parametric model to generate toolpaths and programming,
17 e.g., to a CAD/CAM system comprising appropriate hardware and/or software coupled to
18 appropriate data-driven tools, to fabricate the implant.

19 Defining two additional datum curves 88 and 89, at offset distances from datum
20 curves 86 and 87, is performed to define the top or non-bearing surface 42 of the implant
21 40. This top surface 42 should be closely matched to the bearing surface geometry to be
22 implanted without having to remove an excessive quantity of bone from the chondral
23 surface.

24 Referring to Figures 14c and 19c, implant geometry may be defined whereby the
25 top or bone contacting surface 42 of the implant 40 exhibits an axial symmetry. The
26 central axis AA passes through the point of origin 80 of the implant 40 and when the
27 implant is positioned at the target site, aligns with the original reference axis 20A as
28 defined by the guide pin 20 and fixation screw 10. The central axis AA can then be used
29 to define the preparation tools so that the bone contacting surfaces 42 of the implant 40

1 and the preparation tools can be matched in both configuration and dimension to create a
2 mating fit between the surface of the prepared target site and the bone contacting surfaces
3 42 of the implant. For example, if the preparation tools can be fabricated using some of
4 the same dimensions obtained during the articular surface mapping procedure, the
5 implant geometry and corresponding preparation tool geometry can be mated and
6 optimized so that a minimum vertical thickness of the implant as well as a minimum
7 depth of bone removal is required. This may be advantageous in ensuring good long
8 term clinical results with the implant, as poor quality of fit between bone surfaces and
9 bone-contacting surfaces of traditional orthopedic prosthetic devices has been noted to
10 contribute to early clinical failures.

11 For example, as shown in Figures 14c and 19c the top or bone contacting surface
12 42 of the implant 40, a series of radial cuts 198 may create surfaces that increase
13 resistance of the implant to rotational forces. These features may be located at the outer
14 diameter 190 of the implant 40 to increase their effectiveness. Additional contact
15 surfaces may also be created by one or more protrusions 195 located on the bottom 42 of
16 the implant. Similarly, surface treatments known in the field of orthopedic devices, such
17 as porous and/or osteoconductive coatings, may be utilized on surface 42.

18 As shown in Figure 19b, outer diameter 190 may include a slight outward taper or
19 protrusion 197 along the diametrical surface to enhance load bearing or load transfer
20 properties of the implant to surrounding bone. This feature may also increase the fixation
21 strength of the implant. A fillet 199 (as shown in Figure 19a) that runs around the
22 implant at the intersection of the diametrical surface 190 and the bearing surface 41 is
23 also useful in providing a smooth transition between the host articular cartilage and the
24 implant surface.

25 However, if a greater depth of implant is needed as a result of the defect
26 appearance the offset curves 88 and 89 (as shown in Figure 14a) can be extended to
27 increase the overall thickness of the implant 40 or the offset curves may be eliminated
28 entirely so that the contoured surface is backed by a revolved geometry that is
29 symmetrical to reference axis 20A. Turning to Figure 19c, where the ML curve and AP

1 curve (defined by the obtained measurements) are not axially symmetrical, the thickness
2 of the implant 40 requires adjustment. At the same time, an unnecessarily thick implant
3 requires a greater amount of bone to be removed at the target site. Therefore, the
4 thickness of the implant may be determined by taking the largest obtained measurement
5 and adding a minimal offset amount 208. (The implant is thinnest at the highest point on
6 the ML curve.) This can be similarly accomplished by adjusting the angle Δ (Figure 19a)
7 of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the
8 preparation tool. This also allows for a correction of the implant geometry, to
9 compensate for any non-perpendicular placement of the guide pin with respect to the
10 articular surface.

11 With reference now to Figures 25 and 26, an exemplary algorithm consistent with
12 the invention establishes the minimum thickness of an implant necessary to include all
13 patient data points, receiving as input all of the points measured (typically, four) and
14 identifying the largest value. One such exemplary algorithm is as follows (and as shown
15 in Figures 25 and 26):

```
16     maxval= D6
17         if maxval < D11
18             maxval = D11
19         endif
20         if maxval < D14
21             maxval = D14
22         endif
23     D684 = maxval + .045
```

24
25 In the foregoing exemplary algorithm, a first data point D6 is initially assigned as the
26 maximum value (maxval). If...then type statements are used to compare other data
27 points (D11 and D14) to maxval. If other data points are greater than maxval, the
28 algorithm reassigns maxval to the new larger data point. LLMT represents the height of
29 the lower limit plane along the z-axis, and ULMT represents the height of the upper limit

1 plane along the z-axis. D684 is a dimension that controls the ULMT plane, which is
2 established in the model as the upper surface of the implant. ULMT is positioned as
3 maxval plus an additional arbitrary and/or fixed material offset (.045 in this case).

4 Figures 5c and 5d illustrate an alternative embodiment of the implant 40', having
5 a ML curve between data points 340 and 341 and an AP curve between data points 342
6 and 343, with male-shaped mating component 304 and key-shaped portion 344 for
7 engagement with a reciprocal key-shaped surface in the proximal extension of a fixation
8 screw, protrusions 345 (creating contact surfaces on the top 346 of the implant 40'),
9 radial cuts 347 located at the outer diameter 348 of the implant 40', and radius 349
10 (which may be formed, e.g. using an abrasive wheel) around the intersection of the outer
11 diameter at point 341 and the surface comprising the patient geometry.

12 Referring to Figures 18a and 18b, bone cutting or scoring instrument 250 includes
13 a handle (not shown), a cannulated shaft 111 that extends through the handle, and offset
14 arm 140 housing adjustable blades 141. In the embodiment shown, individual cutting
15 blades 141 are attached to offset arm 140 either fixedly or removably, e.g. via threaded
16 portions 142, into threaded recesses 342 of the offset arm 140, although other attachment
17 means may be used. With guide pin 20 advanced through shaft 113 positioned on the
18 reference axis 20A, a fixed distance from the rotational or references axis 20A to each of
19 the cutting or scoring blades 141 is established. These lengths define the radii that are
20 to be effected in the articular surface, as the scoring instrument 250 is rotated around the
21 guide pin 20, corresponding to the protrusions 195 on the bone contacting surface 42 of
22 the implant 40 creating a matching fit between the bone surfaces of the prepared target
23 site and the bone contacting surfaces of the implant.

24 In an alternative embodiment, as shown in Figure 18c, cutting blades are arranged
25 on carrier 145, configured so that it can be mounted within the slotted surface 114 of
26 offset arm 112, depicted in Figure 17a. In another embodiment, as shown in Figure 18d,
27 cutting blades 141 can be fixedly positioned on offset arm 140. Using the same
28 dimensions obtained during articular surface mapping procedure, the cutting and scoring
29 device 250 can be fabricated to prepare the articular surface to correspond to the implant

1 geometry to optimize fit. In another alternative embodiment, as shown in Figure 18e, a
2 bone cutting instrument 352 corresponds to the alternative embodiment of the implant 40'
3 illustrated in Figures 5c and 5d. Instrument 352 has a handle (not shown), a cannulated
4 shaft 353 that extends through the handle and through the cannulation 355, offset arm
5 354 with blades 350 and 351 corresponding to the protrusions 345 on the bone contacting
6 surface 42 of the implant 40 creating a matching fit between the bone surfaces of the
7 prepared target site and the bone contacting surfaces 346 of the implant 40'.

8 As shown in Figure 14b, an angular dimension 95, relating some locating surface
9 or feature on the hex-shaped cover 30 or on the fixation screw 10, to the four points 81a,
10 81b, 82a and 82b, may also be captured at the time of the initial procedure to assist in
11 orientation of the implant 40 to the fixation screw 10. Guide aperture 46 in implant 40 is
12 located off the reference axis 20A and may serve as the locating feature and/or as a suture
13 passage way in the implantation procedure. Alternatively, a surface or feature created on
14 the implant 40, may serve to reference or align to such locating surface on the hex-shaped
15 cover 30 or the fixation screw 10.

16 Additional data can be taken at the time of the initial procedure, e.g., for
17 fabricating a non-circular implant. Additional data curves can also be defined by
18 measuring the offsets from the reference axis 20A and determining diameters at these
19 offsets. The final implant geometry, although measured using circular techniques, need
20 not be circular.

21 Referring to Figures 10a and 10b, following fabrication of the implant 40, a
22 second procedure is performed. If a cover 30 (or plug) is in place, it is removed,
23 exposing proximal extension 14 (or recess) or some other precision taper or engagement
24 surface located at the proximal end 17 of the fixation screw 10 to which the implant 40 is
25 to be affixed. A pin having a distally mounted element or barb 5 is placed through
26 through hole 16 running through the central lumen of the fixation screw 10 so that the
27 distally mounted element 5 is secured into the screw. The distally mounted element 5
28 carries one or more suture strands 85 that now trail from the fixation screw 10.
29 Alternatively, a pin, braided cable, or flexible wire may also be used. However, sutures

1 may make passing the implant 40 through the incision 200 and subsequent handling
2 easier.

3 Turning to Figures 11a and 11b, the sutures 85 are then threaded through guide
4 aperture 46 of the implant 40 and a knot or bead 49 may be created proximal to the
5 implant, so that tensing one of the free running sutures 85 helps to advance the implant
6 40 toward the proximal extension 14 (or recess) of the fixation screw 10. Alternatively,
7 the suture strands 85 can be passed through the central lumen or shaft of a driving rod or
8 other instrument to aid in seating the implant 40, and positioned in the fixation screw 10
9 thereafter.

10 If necessary, the arthroscopic wound 200 is expanded slightly in either a vertical
11 or horizontal direction, so that the implant 40 may be passed through. A polymeric
12 sleeve (not shown) positioned over the implant may prove helpful in passing the implant
13 through the incision. As shown in Figure 11b, based on the size of the implant 40,
14 anatomy of the knee 50, and retraction of the knee, it may be necessary to position the
15 implant in the intercondylar notch 77 as a staging area prior to final placement. By
16 continuing to manipulate and tension the suture strands 85, the implant 40 can be brought
17 coaxial to the proximal extension 14 of the fixation screw 10.

18 As shown in Figures 15c and 15d, alternatively, driver 130 includes handle 110, a
19 cannulated shaft 111 that extends through the handle and a cannulated seat portion 131
20 attached to the end of the shaft. Tether element 135, which may comprise sutures or
21 wire, is passed through driver 130 and is threaded through implant 40 through guide
22 aperture 46, connecting the implant to the driver toward seat portion 131. The implant
23 40 and the driver 130 are then inserted arthroscopically through incision 200 to the target
24 site. By tensioning tether element 135 at the end 136 of handle 110, the implant 40 is
25 drawn back into seat portion 131 of driver 130. By maintaining tension on tether element
26 135, the implant 40 can then be controllably delivered to the prepared target site. At
27 least the inner surface of seat portion 131 comprises a material that can be impacted to
28 seat the implant 40 without damaging the implant surface.

1 Referring to Figure 12, once coaxial, the implant 40 can be aligned via
2 engagement of the proximal extension 14 on fixation screw 10 and precisions taper 44 on
3 the bottom surface 42 of the implant and any locating feature, and driven into place with
4 a plastic driving rod 91 and mallet 95. A protrusion 92 of high strength material mounted
5 at the distal tip 93 of the driving rod 91 may be necessary to ensure that the rod stays
6 centered on the implant 40 during driving.

7 Finally, as shown in Figure 13, through guide aperture 46 on the upper surface 41
8 of the implant 40, bone-cement 300 may be injected to enhance the contact surface
9 between the implant 40 and the subchondral bone 100. Vents, such as milled slots 13 in
10 the fixation screw 10, and in the walls of the implant central protrusion may be desirable
11 to facilitate the flow of such materials.

12 Alternatively, guide aperture 46 in the implant 40 may be altogether eliminated by
13 using an alternative implant delivery system, as shown in Figures 19d through 19i,
14 corresponding to an implant similar to that shown in Figures 5c and 5d. The alternative
15 system comprises the implant 40'' and a washer 361 for holding a suture 363, the washer
16 361 being adapted to fit into a taper lock ring 360. The ring 360 has a taper lock portion
17 362 having a series of notches 365 along its perimeter, creating flaps 372 that permit the
18 taper lock portion 362 to flex somewhat. The taper lock portion 362 has a diameter
19 gradually tapering from the middle to the proximal end 364 of the ring. The taper lock
20 ring 360 may also have an alignment notch 386 or similar feature for properly aligning
21 the taper lock ring 360 with respect to key-shaped portion 344 of the implant 40'', which
22 is to engage with a reciprocal key-shaped surface in the proximal extension of a fixation
23 screw, so as to seat properly the implant rotationally with respect to the defect site when
24 it is later seated thereon. A washer 361 is disposed between the ring 360 and the implant
25 40'' and has two apertures 366 disposed in a recessed area 367 in the center of the
26 washer. The suture 363 is threaded through the two apertures 366 to form a suture loop
27 368, which remains in the recessed area when the ends of the suture 363 are pulled, so as
28 to keep the suture loop 368 below the top surface 369 of the washer 361. The implant
29 40'' has a diameter at its center portion 370 that is approximately equal to the inner

1 diameter of the ring 360 at its taper lock portion 362. Thus, when tension is applied to
2 the ends of the suture 363, the taper lock portion 362 of the ring 360 may flex outward to
3 receive slidably therein the implant 40'' and washer 361, which subsequently lock into
4 the taper lock portion 362 of the ring, once the center portion 370 of the sides of the
5 implant 40'' is seated within the proximal end 364 of the ring by friction fit, as shown in
6 Figure 19e. It is noted that the center portion 370 of the sides of the implant 40'' to be of
7 a width permitting the implant and washer to travel slidably within the ring 360 to some
8 degree.

9 As shown in Figure 19f, a hex nut 373 may be integrally formed in the center of
10 the washer 361 on its bottom side 374, for mating with an appropriately configured tool
11 for seating the implant 40''. As Figure 19f illustrates, the implant 40'', along with
12 washer 361, ring 360, and sutures 363, is pushed through the incision 200 at the defect
13 site. Next, as shown in Figures 19g – 19i, illustrative of successive steps in the process of
14 seating the implant, a seating tool 380 may be used to seat the implant. Seating tool 380
15 comprises a shaft 385, a handle 381 (which may have a through hole 382, if the same
16 handle and/or shaft is used with interchangeable tips for performing various functions,
17 although a through hole 382 is not integral to seating the implant), and tip 383 suitably
18 configured to drive hex nut 373 (or other mating feature) and having an aperture 384
19 through which the ends of the suture 363 may be threaded. Once the tip 383 of the tool
20 380 is introduced into the incision 200, the sutures 363 may be used as a guide for seating
21 the tip 383 of the tool 380 onto the hex nut 373, which may be accomplished by
22 alternately pulling on each end of the suture 363 to toggle the tip 383 of the tool 380 back
23 and forth. Once the tip 383 of the tool 380 is seated onto the hex nut 373, the tool 380
24 may be rotated in either direction to seat the implant assembly properly (comprising
25 implant 40'', taper lock ring 360, and washer 361) at the defect site. This may be
26 effected by rotating tool 380 until alignment notch 386 and corresponding key-shaped
27 portion 344 of the implant 40'' are aligned with the corresponding reciprocal key-shaped
28 surface in the proximal extension of the fixation screw, whereby the implant should slide
29 into place, thereby properly seating the implant rotationally with respect to the defect site.

1 As shown in Figure 12 with respect to the prior described embodiment, once properly
2 seated, the implant 40'' can be driven into place with a plastic driving rod 91 and mallet
3 95, and as shown in Figure 13 with respect to the prior described embodiment, bone
4 cement 300 may also be placed prior to the final seating of the implant 40'' to enhance
5 the contact surface between the implant 40'' and the subchondral bone 100. It should be
6 understood that the taper lock ring 360, washer 361, and sutures 363 described with
7 respect to this embodiment allow the implant to be noncannulated but still easily handled.
8 These elements are not required to be constructed as illustrated herein, and may be
9 replaced by adhesive components, suction components, or other components serving the
10 same function.

11 As Figures 21 and 22 illustrate, a unitary (one-piece) implant 400 may also be
12 constructed, thereby obviating the need for a fixation screw, taper lock ring, washer, and
13 suture. In this embodiment, implant 400 has key-shaped portion 401 for engagement
14 with a reciprocal key-shaped surface 411 in an aperture 412 at the defect site 410, a
15 plurality of barbs 402 (or other mating features, e.g., one or more threads, ribs, fins,
16 milled slots, tapered distal features, features to prevent rotational movement of the
17 implant, or features to increase friction between the implant and the aperture at the defect
18 site) for producing outward tension within the aperture 412 at the defect site 410 and for
19 increasing the contact surface area of the implant 400 with respect to the aperture 412 at
20 the defect site 410. In this embodiment, an aperture 412 having a key-shaped surface 411
21 or other feature for mating with the implant is created directly in the defect site 410, by
22 boring, abrasion, or other techniques for forming an appropriately shaped aperture in the
23 chondral bone 410 for receiving an implant 400 having a corresponding key-shaped or
24 other mating feature 401. It should also be recognized that, in this or other embodiments,
25 the fixation screw could be replaced with a tensioned member attachment, e.g., anchored
26 to the distal femoral cortex. Alternatively, the fixation screw could be configured as a
27 guide wire, only to define the axis AA corresponding to an axis about the point of origin
28 in the implant to be used (as shown in Figures 14c and 19c), but not to provide
29 mechanical anchoring to or for the implant.

1 Figure 23 illustrates other alternative embodiments for an implant consistent with
2 the invention, showing a perspective view of the components of an exemplary composite
3 implant, in one embodiment of the present invention. As shown, implant 500 comprises
4 top 501 and bottom 502 portions. Top portion 501 has a bottom surface 503 which may
5 be glued, welded, bonded, or otherwise attached to top surface 504 of bottom portion
6 502, while bottom surface 505 of bottom portion 502 comprises the patient geometry and
7 is the load-bearing surface of the implant, as set forth hereinabove. Top 504 and bottom
8 505 surfaces of the bottom portion 502 may comprise, in whole or in part, bioengineered
9 material, while top portion 501 may comprise a material such as titanium. In such a
10 configuration, top portion 501 may be fabricated and/or manufactured (e.g. in large
11 quantities) as a universal, generic, standard supply item for medical practitioners, which
12 merely needs to be attached to a custom-machined bottom portion 502 comprising the
13 patient-specific geometry. Surfaces 503 and 504 may be flat or may comprise other
14 mating features, shapes or configurations.

15 Further composite implant embodiments are illustrated in Figure 24, wherein
16 implant 600 comprises the patient-specific geometry 603 and a uniform thickness
17 material bottom portion 602 comprising the bottom or bearing surface 606. The bottom
18 surface 603 of top portion 601 mates with the top surface 604 of bottom portion 602, and
19 surfaces 603 and 604 may be flat or may comprise other mating features, shapes or
20 configurations. Lip 605 of bottom portion 602 has an inside diameter substantially the
21 same as the outside diameter of top portion 601, so that top portion 601 fits slidably into
22 bottom portion 602, whereby the two portions 601 and 602 may be glued, welded,
23 bonded, or otherwise attached to one another. Bottom surface 606, being of uniform
24 thickness, reflects the patient-specific geometry which surface 603 comprises and is the
25 load-bearing surface of the implant.

26 Other materials from which an implant consistent with the invention may be
27 constructed, in whole or in part, include ceramic, e.g. aluminum oxide or zirconium
28 oxide; metal and metal alloys, e.g. Co-Cr-W-Ni, Co-Cr-M, CoCr alloys, CoCr
29 Molybdenum alloys, Cr-Ni-Mn alloys, powder metal alloys, 316L stainless steel, Ti 6Al

1 – 4V ELI; polymers, e.g., polyurethane, polyethylene (wear resistant and cross-linked),
2 thermoplastic elastomers; biomaterials, e.g. polycaprolactone; and diffusion hardened
3 materials, e.g. Ti-13-13, Zirconium and Niobium. Coatings used may include, e.g.,
4 porous coating systems on bone-contacting surfaces, hydrophilic coatings on load-
5 bearing surfaces, hydroxyapatite coatings on bone-contacting surfaces, and tri-calcium
6 phosphate on bone-contacting surfaces. Additionally, components of the invention may
7 be molded or cast, hand-fabricated, or machined.

8 Alternatively, measurement methods may be utilized whereby radius
9 measurements are taken with respect to an axis AA corresponding to an axis about the
10 point of origin in the implant to be used (as shown in Figures 14c and 19c). The
11 technique is used in reverse, whereby aiming devices are used to place axis AA with
12 respect to prefabricated generic-geometry implants.

13 It is noted that, although the invention is herein described as utilizing a single
14 reference axis, multiple reference axes may be used for measuring, mapping, or cutting a
15 single defect or an articular surface having multiple defects, as well as for fabricating a
16 single implant, or multiple implants for a single articular surface, consistent with the
17 invention. In other embodiments, methods for mapping the defect and/or articular
18 surface other than those described hereinabove are possible, e.g., MRI or CT scanning,
19 fluoroscopy, ultrasound, bone density, other stereotactic systems, nuclear medicine, or
20 other sound or light wave-based imaging methods.

21 It is further noted that, although the invention is described herein as utilizing the
22 specific geometry of a patient's articular surface to fabricate an implant for that patient, it
23 is contemplated that data from a plurality of patients may be analyzed statistically and
24 utilized in fabricating and/or manufacturing (e.g. in large quantities) one or more
25 universal, generic, or standard supply item type implants for medical practitioners to use
26 in a procedure consistent with the invention. For such implants, as well as for patient-
27 specific implants as described herein, pre- or post-implantation trimming may be required
28 to correct for minor variations that may occur as between the implant and the subchondral
29 bone (or other articular surface).

1 It should be understood that, although the various tools described hereinabove,
2 e.g., for measuring, cutting, and seating, are described as separate devices, a single
3 handle, shaft and/or instrument may be configured to serve as a universal mounting tool
4 for a series of devices for performing various functions consistent with the invention.

5 Generic Bone Resurface Implant, Cutting Tool, and Procedure

6 Figures 27a-48 depict another exemplary embodiment of the present invention. In
7 this embodiment a generic bone implant (or set of standardized implants) is created (or
8 selected) based on developing an axis normal to the surface and collecting only one data
9 point. In the above-described embodiments, a non-normal axis was utilized, and four
10 data points were required to develop ML and AP curves. Further, a generic cutting tool is
11 used to cut the bone at this site to a point where a generic implant can be used. Several
12 improved tools relating to the procedure for using such an implant (as well as for using
13 implants as described hereinabove) are further described in this section and illustrated in
14 the corresponding figures.

15 Figure 27a depicts an exemplary drill guide device 700 according to this
16 exemplary embodiment. The guide 700 includes a contact surface 702 of known
17 diameter d on the distal end 708 of the guide, where diameter d is generally the width of
18 the widest portion of the site of the lesion. The distal end 708 of the guide is generally a
19 hollowed-out toroidal structure attached to a handle 706. A central lumen 704 runs the
20 length of the guide from the attachment point of the distal end 708 to the handle 706, and
21 through the handle 706. The guide device may be constructed in a number of other ways,
22 including, e.g., a distal end 708 comprising a transparent material, e.g., polycarbonate or
23 another clear plastic. For example, as shown in Figure 27b, a guide device 700' may
24 comprise a distal end 708' (which could comprise either an opaque or a transparent
25 material) having a plurality of cutaway areas 743 to improve visibility and the accuracy
26 of drill location with respect to the site of a lesion. The guide device may also comprise a
27 tripod-like construction, or other construction comprising fins, or projections. It should
28 be noted that, instead of a central lumen being used to locate the working axis, a

1 cylindrical bore located at some distal location of the guide may serve to create a working
2 axis that is not necessarily coaxial to the handle or connecting shaft of the instrument.

3 Referring now to Figures 28a and 28b, the present embodiment operates on the
4 assumption that to a first approximation an anatomical model of some articular surfaces
5 (e.g., knee, hip, etc.) can be assumed to be locally spherical. In other words, as shown in
6 Figures 28a and 28b, the AP plane and ML plane, respectively, are depicted, wherein
7 each corresponds to a model of the articular surface of a femoral region. These figures
8 break up these cross-sections into a plurality of radii of arcs defining the articular surface,
9 i.e., R_1 - R_4 in the AP plane, and R_5 - R_7 in the ML plane. In this embodiment, the inventors
10 herein have found that surfaces in some regions can be assumed to be substantially
11 locally spherical. Thus, for example, the present embodiment assumes that R_3
12 approximately equals R_6 (i.e., R_3 is within 50% of R_6). Under these assumptions, a
13 normal axis can easily be developed. Once developed, one data point then needs to be
14 defined to obtain the relevant geometry of an implant, as will be described below. If R_3
15 is not within 50% of R_6 , an alternative method for developing an axis normal to the
16 surface of the lesion site, as described hereinbelow with reference to Figures 49-53, may
17 be used.

18 Figures 29-34 depict the use of the drill guide, the generic implant, and
19 procedures therefor, according to this exemplary embodiment. In Figure 29, the drill
20 guide 700 is brought up to a lesion site 712 of the articular surface 710. The guide 700 is
21 positioned so that the distal end 702 covers the lesion site 712, such that the contact
22 surface of the distal end 702 makes contact at a plurality of points around the lesion site
23 712 on the articular surface 710. As shown in Figure 30, with slight pressure the guide
24 700 becomes stable and fixed on the articular surface 710. Once seated in position, a
25 guide pin 714 is driven through the central lumen of the guide to create a working axis
26 that is generally normal to the articular surface 710 at the point of contact of the guide
27 pin. As Figure 31 illustrates, a standard bore drill (not shown) can be placed over the
28 guide pin 714 to create a pilot hole 716 for the screw (not shown).

1 With reference now to Figure 32, as with the previous embodiments described
2 above, a screw 720 is driven into the pilot hole 716. A cap 722 having a male component
3 719 adapted to mate with the female taper 718 of the screw 720 is placed on the screw
4 720. The screw is driven to the appropriate depth, such that the top surface of the cap
5 722 is substantially aligned with the articular surface 710, within the lesion site 712,
6 thereby ensuring congruency of the implant to the joint. Turning now to Figure 33, the
7 cap 722 is removed, and a rod 730 having a mating taper 731 on its distal tip is inserted
8 into the screw 720. The guide 700 is positioned over the rod 730 so that the distal end
9 702 covers the lesion once again. As illustrated in Figure 34, since the length of the rod
10 730 and the length of the guide 700 are known, a measurement of the exposed end length
11 of the rod (l) may be taken. This will provide the information needed with respect to the
12 implant geometry, by indicating the distance between the seating depth in the screw and
13 the tangent point of the implant surface. As shown in Figure 35, since the axis, z , is
14 defined (by the drill guide) as normal to the surface of the implant at a plurality of points,
15 all dimensions defining the AP and ML curves may be assumed to be equal, such that
16 only one dimension, l , is left to define the implant geometry. Variations from knee to
17 knee and within a knee may be reflected in changes in l . For example, the implant 736 of
18 Figure 36 may be compared to the implant 737 of Figure 37. For implant 736 of Figure
19 36, the value of l_1 represents a relatively "flat" region on the articular cartilage, where the
20 radius of the arc R_{AC1} is a relatively large number. However, for implant 737 of Figure
21 37, the value of l_2 represents a more curved region on the articular cartilage, where the
22 radius of the arc R_{AC2} is a smaller number than R_{AC1} . As indicated by clinical data, there
23 is a range of values for l that suggests 5 to 6 values of l that will fit a majority of people.
24 Thus, generic, off-the-shelf sized implants may be made. A single procedure technique
25 involving establishing the normal axis, measuring l , and selecting the appropriate size
26 implant is therefore feasible.

27 As illustrated in Figure 38, an exemplary cutting or reaming tool 740 (e.g., as
28 described hereinabove with respect to Figures 15b and 16) is used to prepare the lesion
29 site 712 to receive the implant (not shown). The cutting or reaming tool 740 may be

1 configured so that, when coupled to the axis defined by the guide pin, it can be used for
2 cutting operations. The tool 740 may have a cannulated shaft and a distal offset arm
3 having a cutting or blade surface (not shown) having a radius corresponding to the radius
4 of the implant to be used, such that the articular cartilage may be circumscribed by
5 rotation of the tool 740 for cleanly cutting the surrounding articular cartilage in
6 preparation for receiving the implant. The tool 740 may be configured so that, when
7 coupled to the axis defined by the guide pin, it can be used for cutting operations. The
8 proximal face of the screw 720 may serve as a depth stop for the proximal portion of the
9 tool 740, thereby defining a cutting/reaming depth corresponding to the thickness of the
10 implant, *l*.

11 Those skilled in the art will recognize that the cutting tool may be motorized in
12 certain embodiments, and/or alternatively, as illustrated in Figure 39, an exemplary
13 cutting tool 744 may comprise a cannulated shaft 749, a circular blade portion 745 having
14 a leading edge 746 comprising a blade surface turned on the distal-most portion. Such a
15 tool 744 may further comprise a handle portion 747 and may be adapted to be turned by
16 hand by the operator of the tool by means of rotating the handle 747, or alternatively,
17 may be motorized in certain embodiments.

18 Figure 40 illustrates an exemplary cleaning tool 770 for cleaning the female taper
19 (not shown) of the screw 720 prior to delivery of the implant. The distal end 771 of an
20 exemplary cleaning tool 770 comprises a semi-rigid material formed into a shape adapted
21 to enter into the female taper of the screw 720 and be manipulated by the operator of the
22 tool, to remove tissue or other debris therefrom, thereby ensuring a good mate of the
23 female taper 720 of the screw and the male taper of the implant to be delivered (not
24 shown).

25 Figures 41-43 illustrate an exemplary suction tool 760 for holding the implant by
26 means of a suction force and delivering it to the lesion site, as well as the steps of an
27 exemplary procedure for using the suction tool 760 to deliver an implant. As illustrated
28 in Figure 41, an exemplary suction tool 760 comprises an elastomeric suction tip 761 at
29 its distal portion 767, a proximal surface 768, an inlet 762 for mating with a suction tube

1 763 connected either to a hospital wall suction supply 764 or other suction system, and a
2 switch or valve 765 for controlling the suction force. As Figure 42 illustrates, when the
3 suction force at the elastomeric suction tip 761 is activated by the switch or valve 765,
4 the implant 742 is held in place, and thus, the suction tool 760 may be used to hold the
5 implant prior to, and during, the delivery thereof. As shown in the cross-sectional view
6 of Figure 43, the distal portion 767 of an exemplary suction tool 760 may comprise a
7 rigid tip 766 (which may comprise, e.g., plastic material) disposed within the elastomeric
8 suction tip 761. Force may be applied to the rigid tip 766 (e.g., by striking or pressing on
9 the proximal surface 768 of the tool 760) in order to seat the implant 742 within the
10 lesion site, once the male taper 769 of the implant 742 and its corresponding mating
11 component(s) 778 are properly aligned with the female taper of the screw (not shown)
12 and its corresponding mating component(s). Since the suction tip 761 is elastomeric
13 (e.g., rubber), upon application of such force, the material will compress, allowing impact
14 to be transferred to the implant 742 for purposes of seating it. It is noted that, in addition
15 to its utility in delivering an implant, a suction tool 760 as described herein (or a suction
16 tool similar thereto) might also be used at some point during the process of removing an
17 implant (e.g., in the event the implant is not fully seated).

18 Figure 44 illustrates an exemplary implant 742 driven into the lesion site 712 of
19 the articular surface 710 once the site 712 has been sufficiently reamed or cut.

20 Figure 45 illustrates an exemplary implant removal or revision tool 750
21 comprising a shaft portion 751 and a distal portion 753, and Figure 46 is a cross-sectional
22 view illustrating the exemplary tool 750 with a removed implant 742 being held in place
23 therein. As shown, the distal portion 753 of the tool 750 may comprise an approximately
24 cylindrical structure with a circular blade portion 752 having a leading edge 758
25 comprising a blade surface turned on the distal-most portion and a lip portion 755
26 disposed proximally with respect to the leading edge 758. A plurality of slits 754 parallel
27 to the longitudinal central axis of the distal portion 753 are disposed along the length of
28 the cylindrical structure, so as to permit sufficient outward expansion of the distal portion
29 753 to accommodate the top edge of the implant 742 therein. Thus, when the distal

1 portion 753 of the tool 750 is forced onto an implant 742 to be removed, and driven down
2 over the implant 742, the distal portion 753 will snap/lock into place once the lip portion
3 755 of the distal portion 753 of the tool 750 passes the top edge of the implant 742 being
4 removed, thereby holding the implant 742 in place within the distal portion 753 of the
5 tool 750, as shown in Figure 46. At this point, a device such as a slap-hammer or slide
6 hammer (not shown) may be used to unseat the implant 742. An exemplary such device
7 may comprise a shaft having a weight slidably disposed thereon, wherein one end of the
8 shaft is connected to the proximal end (not shown) of the tool 750 and the other end of
9 the shaft comprises a stop for preventing the weight from moving off the shaft, and
10 wherein the weight is propelled away from its connection point with the proximal end of
11 the tool 750, such that it stops abruptly at the stop and exerts a pulling force on the
12 implant.

13 Alternative Embodiment of Screw

14 Figures 47 and 48 illustrate an exemplary alternatively-keyed embodiment of the
15 screw 720' (c.f., key feature 315 of screw 10', as shown in Figure 9c) and the exemplary
16 alternatively-keyed implant 742' to which it is adapted to mate. As shown, the male
17 taper 769' of the implant 742' is coupled at its distal end to an offset mating feature 778'
18 for mating with a corresponding offset mating feature 779' of the screw 720'. The mating
19 feature 778' of the implant 742' comprises a generally cylindrical structure (and may
20 further comprise a rounded or chamfered distal end portion 777' and/or other geometric
21 features, i.e., recesses and/or protrusions) and is both offset from the central longitudinal
22 axis of, and diametrically smaller than, the male taper 769' of the implant 742'. As
23 Figure 48 illustrates, a generally cylindrical recessed mating feature 779' (or similar
24 mating recess(es) and/or protrusion(s), e.g., a rounded or chamfered distal end portion
25 780) corresponding to the offset distal mating feature 778' of the implant 742' is disposed
26 within the innermost portion of the female taper 718' of the implant 742', and offset from
27 the central longitudinal axis of the female taper 718'. The female mating feature 779' of
28 the screw is provided to mate with the offset male distal mating feature 778' of the
29 implant 742', so as to seat the taper 769' of the implant 742' at a fixed location within the

1 screw 720', thereby preventing rotation of the implant 742' with respect to the screw
2 720'. Along with the mating features 778', 779, the taper structures provided may serve
3 to prevent movement of the implant 742' with respect to the screw 720' in all directions.
4 A screw 720' consistent with the present invention may comprise a titanium alloy, e.g., a
5 316L stainless steel alloy or a cobalt-chrome alloy.

6 Alternative Method for Developing Axis Normal to Lesion Site Surface

7 Figures 49-53 illustrate an alternative method for developing an axis normal to the
8 surface of the lesion site using a biaxial measuring tool. This method has particular
9 utility for lesion sites where the radii of arcs defining the articular surface, R_{ML} and R_{AP} ,
10 are different, i.e., the region is not locally spherical. (This would be the case, e.g., if R_3 is
11 not within 50% of R_6 , as illustrated in Figures 29a and 29b and described hereinabove.)
12 To develop an axis normal to the surface, a biaxial measuring tool 800 is provided. The
13 tool 800 comprises an outer shaft 805 coupled fixedly to an outer component 801 having
14 a set of arms 803, and an inner shaft 806 slidably disposed within the outer shaft 805,
15 wherein the inner shaft is coupled fixedly to an inner component 802 having a set of arms
16 804. The arms 803, 804 of the outer 801 and inner 802 components may take several
17 forms, and one exemplary form for the arms 803, 804 is illustrated in Figures 49-53,
18 wherein the distal portion of each arm 803, 804 tapers outward and connects to one of
19 four contact portions 808. The contact portions 808 may be, e.g., as shown, one of four
20 arcuate sections of a generally toroidal member (which may be solid or hollow) having a
21 generally circular cross-section. (The lengths of the arcuate sections do not necessarily
22 need to be equal to one another, e.g., as illustrated in the exemplary contact portions 808
23 of Figures 49-53, the arcuate lengths of the contact portions 808 corresponding to the
24 inner component 802 are shorter than those contact portions 808 corresponding to the
25 outer component 801.) The inner shaft 806 may be biased forward so as to tend to extend
26 from the outer shaft 805, or may alternatively be advanced manually without spring bias.
27 The inner component 802 is slid proximally or distally with respect to the outer
28 component 801, until all of the contact portions 808 make contact with the articular
29 surface (not shown). In this manner, the articular surface curvatures may be separated

1 into AP elements and ML elements, such that four separate contact points may be
2 extrapolated from the four contact portions 808, based on the relative positions of the
3 inner 802 and outer 801 components, and an axis normal to the surface of the lesion site
4 may be defined. The shaft of the tool 800 may be cannulated (not shown), so as to allow
5 a guide pin or wire (or a boring tool) to pass therethrough and into the articular surface,
6 as described hereinabove with respect to Figures 27a to 31. As shown in Figure 53, if the
7 inner 802 and outer 801 components are aligned such that the four contact portions 808
8 meet to form a complete toroidal member or ring, the articular surface must be locally
9 spherical, i.e., R_{ML} and R_{AP} (as shown in Figure 49) are equal, and it is therefore not
10 necessary to use the biaxial tool 800.

11 It should be noted that, alternatively, contact surfaces may be constructed of some
12 pliable, or malleable material(s) so that independently moving rigid mechanical members
13 are not necessary. As long as the contact surfaces provide a normalizing force to some
14 central shaft when the contact surfaces are applied to the articular surface, a normal axis
15 could be defined.

16 In another embodiment, this biaxial guide could be replaced by a series of sized
17 "trials" or gauges of predefined surfaces of varying dimensions, which are simply pressed
18 onto the articular surface to visually determine an appropriate fit. These gauges may
19 resemble an implant, as described herein, without any features (e.g., fixation element or
20 screw) on the underside, and may contain a handling tab or other element for holding the
21 gauge. The contact surfaces of these gauges may have a circular cross section, an ovalar
22 cross section, or another cross-section comprising a plurality of points to surround a
23 defect in an articular surface, and the plurality of points may or may not lie in the same
24 plane. Although they may be less precise or less accurate than other measuring methods
25 described herein, it is contemplated that implant selection could be made directly from
26 these gauges.

27 Digital Measuring System

28 Figures 54-61 illustrate an exemplary digital measuring system consistent with the
29 present invention. As shown, the system 810 comprises a base unit 811 coupled to the

1 handpiece 812 via a cable 813. As described further hereinbelow, the base unit 811 may
2 comprise a tear strip 814 in or on the chassis for detaching a printed paper tape
3 comprising measurement data. Such a system may reduce or eliminate potential for
4 surgical or other human error with respect to the implementation of the present invention.

5 Figure 55 is an exploded view of an exemplary handpiece 812 in a digital system
6 consistent with the present invention. The linear measuring elements of the handpiece
7 812 are nested concentrically and coaxially to the rotary measuring elements, so that
8 when the probe assembly 818 is translated and rotated with respect to the main body 822
9 of the handpiece, the θ and z dimensions are simultaneously recorded. The handpiece 812
10 comprises a main body 822 containing a linear reading head 813 coupled to a linear
11 reader 814, a linear index strip 815, a rotary reading head 821 coupled to a rotary reader
12 816, and a rotary index strip 817. The probe assembly 818 comprises a contact tip 819
13 coupled to an inner shaft 820 running along the length of the handpiece 813 disposed
14 within the main body 822. The shaft 820 comprises a mating feature 834 at its distal end
15 that is keyed to fit in the mating feature of an implanted screw, such that the shaft 820
16 provides a rotational axis. The shaft 820 is rigidly connected to the main body 822 of the
17 handpiece 812 via a nut 823 at its rear. The handpiece 813 is coupled to, and transfers
18 motion both rotationally and axially from, the contact tip 819 via the shaft 820. In this
19 manner, the linear 815 and rotary 817 strips, which may comprise, e.g., mylar polyester
20 film having thereon a very fine printed pattern, pass through the linear 813 and rotary 821
21 reading heads, respectively, such that the heads 813, 821 read the pattern on the strips
22 815, 817 and output data representing the rotational and axial travel of the contact tip
23 819.

24 Exemplary strips and heads may include those manufactured by U.S. DigitalTM
25 Corporation of Vancouver, Washington, USA. Figure 55a is a cutaway view illustrating
26 an exemplary printed linear index strip 815 passing through an exemplary linear head 813
27 for reading, and Figure 55b is a cutaway view illustrating two alternative exemplary
28 printed rotary index strips 817, 817' of varying sizes passing through an exemplary rotary
29 head 821 for reading. Figure 55c illustrates an exemplary linear index strip 815

1 comprising concentric "bullseye" circles 830, reference lines 831, a text area 832, and a
2 pattern area 833. Figure 55d illustrates an exemplary rotary index strip 817 comprising
3 an opaque area 823, index areas 824, a pattern area 825, a text area 826, crosshairs 827,
4 concentric "bullseye" circles 828 and a central aperture 829.

5 Turning now to Figures 56a and 56b, a rotational groove 840 and a linear groove
6 841 are provided on the handpiece 812, such that the probe assembly 818 may slide onto
7 the shaft 820 of the handpiece 812 and snap into the linear 841 and rotational 840
8 grooves.

9 Figures 57 and 58 illustrate top and side views, respectively, of the assembled
10 exemplary handpiece 812.

11 Figures 59 and 60 illustrate top and side cross-sectional views, respectively, of the
12 assembled exemplary handpiece 812.

13 Figure 61 illustrates a cutaway view of an exemplary base unit 811 in an
14 exemplary digital measuring system consistent with the present invention. The base unit
15 811 comprises a power supply 850 (the system may be battery or AC-line powered), a
16 paper roll 851, a thermal printer 852, a feed loop dowel 853 for threading the paper roll
17 851 into the thermal printer 852, a set of controls or buttons 854, and one or more
18 displays 855 (e.g., LED/LCD). The base unit 811 further comprises appropriate
19 hardware and/or software to compare measured values to known values, as well as to
20 compare sweeps to one another to ensure procedural accuracy. Further, the displays 855
21 and/or paper printouts from the thermal printer 852 may be adapted to display to the user,
22 based on measured data, the ideal size of the generic implant to use. If a custom implant
23 is required, a printout of the data set may be generated using the printer 852. The base
24 unit 811 may further comprise other means of recording data (not shown), e.g., floppy
25 disk, hard disk, memory/flash card, etc., and may further comprise appropriate hardware
26 to provide output signals (e.g., via RS-232, USB, etc.) to external hardware. Instead of
27 the strips, heads, and other recording elements described in the exemplary digital system
28 hereinabove, other digital measurement methods may be used, including reflective light
29 or sound methods, and percutaneous methods (e.g., using a hypodermic needle in

1 conjunction with an MRI, CT, ultrasound, or other scanning method, wherein the needle
2 or other handheld device comprises sensing elements for mapping the articular surface).

3 It should be noted that in the digital measuring system and method described
4 hereinabove (as well as any of the mapping/measuring techniques herein), a second (or
5 third, etc.) set of data points may be taken, and the subsequent set(s) of data points
6 compared with the original data points taken, to reduce the margin of error from taking
7 only a single set of data points. Thus, a software algorithm in a system or method
8 consistent with the invention may comprise appropriate routines to effect such
9 comparisons, for error reduction purposes.

10 Those skilled in the art will recognize that the present invention is subject to other
11 modifications and/or alterations, all of which are deemed within the scope of the present
12 invention, as defined in the hereinafter appended claims.

13 What is claimed is:
14

- 1 1. A guide device for locating a working axis substantially normal with respect to an
2 articular surface of bone, said device comprising:
3 a shaft having an end and an aiming feature for projecting an axis; and
4 a contact surface comprising a plurality of points radially extending from the
5 aiming feature of said shaft;
6 wherein said plurality of points of said contact surface surrounds a defect in an
7 articular surface.
- 8 2. A guide device as claimed in claim 1, wherein said contact surface is formed by a
9 generally toroidal member coupled to the end of said shaft.
- 10 3. A guide device as claimed in claim 1, wherein said contact surface comprises at
11 least one fin, projection, or deformable element.
- 12 4. A guide device as claimed in claim 1, wherein said shaft is cannulated, and
13 wherein said guide device is adapted to receive a tool for creating a pilot hole through
14 said cannulated shaft and permit said tool to be driven substantially normal into an
15 articular surface of bone when at least three of said plurality of points of said contact
16 surface make contact with said articular surface of bone.
- 17 5. A guide device as claimed in claim 1, wherein said guide device is adapted to
18 receive a guide pin or wire through said aiming feature and permit said guide pin or wire
19 to be driven substantially normal into an articular surface of bone when at least three of
20 said plurality of points of said contact surface make contact with said articular surface of
21 bone.
- 22 6. A guide device as claimed in claim 1, wherein said contact surface comprises at
23 least one aperture or transparent portion formed therein, permitting the viewing of at least
24 a portion of an articular surface therethrough.
- 25 7. A guide device as claimed in claim 1, wherein said plurality of points of said
26 contact surface corresponds to the plurality of points making contact with an articular
27 surface along the perimeter of an implant.

- 1 8. A guide device as claimed in claim 1, wherein said plurality of points of said
2 contact surface corresponds to the plurality of points along the perimeter of a portion of
3 an articular surface to be removed.
- 4 9. A guide device for locating a working axis substantially normal with respect to an
5 articular surface of bone, said device comprising:
6 a shaft having an aiming feature for projecting an axis; and
7 a contact surface comprising a plurality of points radially equidistant from the aiming
8 feature of said shaft.
- 9 10. A guide device for locating a working axis substantially normal with respect to an
10 articular surface of bone, said device comprising:
11 a shaft having an aiming feature for projecting an axis; and
12 a contact surface comprising a plurality of points equidistant from the aiming feature of
13 said shaft.
- 14 11. A guide device for locating a working axis substantially normal with respect to an
15 articular surface of bone, said device comprising:
16 a shaft having an end and a central longitudinal axis; and
17 a contact surface comprising a plurality of points radially equidistant from said
18 central longitudinal axis.
- 19 12. A guide device for locating a working axis substantially normal with respect to a
20 non-spherical articular surface of bone, said device comprising:
21 a first element having a longitudinal axis and a contact surface mounted to a shaft;
22 and
23 a second element with a contact surface movable with respect to the contact
24 surface of the first element, wherein, when said guide device is placed on a non-spherical
25 articular surface, both contact surfaces make contact with said articular surface.
- 26 13. A guide device as claimed in claim 12, wherein each said contact surface
27 comprises a plurality of arcuate sections of a generally toroidal member, wherein said
28 generally toroidal member is formed when said contact surfaces make contact with a
29 locally spherical articular surface.

- 1 14. A guide device as claimed in claim 12, wherein one said contact surface is biased
2 in one direction with respect to the other said contact surface.
- 3 15. A guide device as claimed in claim 12, wherein said contact surfaces are adapted
4 such that the contact surface of the first element make contact with a plurality of points
5 along either one of the AP or ML curves of an articular surface, while the contact surface
6 of said second element make contact with a plurality of points along the other of the AP
7 or ML curves of said articular surface.
- 8 16. A guide device as claimed in claim 12, wherein said first or said second element
9 comprises a cannula, wherein said guide device is adapted to receive a tool for creating a
10 pilot hole through said cannula and permit said tool to be driven substantially normal into
11 an articular surface of bone.
- 12 17. A guide device as claimed in claim 12, wherein said first or said second element
13 comprises a cannula, wherein said guide device is adapted to receive a guide pin or wire
14 through said cannula and permit said guide pin or wire to be driven substantially normal
15 into an articular surface of bone.
- 16 18. A guide device as claimed in claim 12, wherein said first or said second element
17 comprises at least one aperture or transparent portion formed therein, permitting the
18 viewing of at least a portion of an articular surface therethrough.
- 19 19. A guide device as claimed in claim 12, wherein the outermost dimensions of said
20 contact surfaces surround a defect in an articular surface.
- 21 20. A guide device as claimed in claim 15, wherein the plurality of points contacting
22 said contact surfaces corresponds to the plurality of points abutting an articular surface
23 along the perimeter of an implant.
- 24 21. A guide device as claimed in claim 15, wherein the plurality of points contacting
25 said contact surfaces corresponds to the plurality of points along the perimeter of a
26 portion of an articular surface to be removed.
- 27 22. A guide device for locating a working axis substantially normal with respect to an
28 articular surface of bone having an anterior-posterior (AP) curve and a medial-lateral
29 (ML) curve, said device comprising:

1 a cannulated outer shaft, said outer shaft having a central longitudinal axis and an
2 outer component at its distal end, said outer component comprising a set of arms; and
3 a cannulated inner shaft slidably disposed within the cannula of said outer shaft,
4 said inner shaft having an inner component at its distal end and sharing the central
5 longitudinal axis of said outer shaft, said inner component comprising a set of arms.

6 23. A method for replacing a portion of an articular surface of bone, said method
7 comprising:

8 establishing a working axis substantially normal to an articular surface of bone;

9 excising only a portion of said articular surface adjacent said axis, thereby
10 creating an implant site; and

11 installing an artificial implant into said implant site.

12 24. A method as claimed in claim 23, wherein said implant comprises a bone-facing
13 distal surface adapted to mate with said implant site, said surface comprising at least one
14 mating feature; and a proximal surface having a contour substantially matching or based
15 on the original surface contour of said excised portion of said articular surface.

16 25. A method as claimed in claim 24, wherein said mating feature is selected from the
17 group consisting of: barbs, threads, ribs, fins, milled slots, tapered distal features, features
18 to prevent rotational movement of said implant, or features to increase friction and/or
19 contact surface between said implant and the aperture at said implant site.

20 26. A method for replacing a portion of an articular surface of bone, said method
21 comprising:

22 establishing a working axis substantially normal to an articular surface of bone;

23 excising only a portion of said articular surface adjacent said axis, thereby
24 creating an implant site;

25 selecting an implant corresponding to the dimensions of said implant site from a
26 set of variously-sized implants; and

27 installing said selected implant into said implant site.

- 1 27. A method as claimed in claim 26, wherein said establishing step is performed
2 using a tool comprising a shaft having an aiming feature and a distal surface comprising a
3 plurality of points radially extending from said aiming feature.
- 4 28. A method as claimed in claim 26, wherein said implant comprises a bone-facing
5 distal surface adapted to mate with said implant site, said surface comprising at least one
6 mating feature; and a proximal surface having a contour substantially matching or based
7 on the original surface contour of said excised portion of said articular surface.
- 8 29. A method as claimed in claim 28, wherein said mating feature is at least one of
9 the features selected from the group comprising: barbs, threads, ribs, fins, milled slots,
10 tapered distal features, features to prevent rotational movement of said implant, or
11 features to increase friction between said implant and the aperture at said implant site.
- 12 30. A method as claimed in claim 26, wherein said establishing step is performed
13 using a tool comprising a shaft having an end and an aiming feature; and at least one
14 contact surface coupled to the end of said shaft, said contact surface comprising a
15 plurality of points radially extending from said aiming feature.
- 16 31. A method as claimed in claim 26, wherein said establishing step is performed by
17 installing a guide pin or wire into said articular surface along said axis.
- 18 32. A method as claimed in claim 26, wherein said excising step is performed using a
19 cutting tool that rotates about said axis.
- 20 33. A method as claimed in claim 26, wherein said installing step comprises driving a
21 fixation element into said articular surface along said axis.
- 22 34. A method as claimed in claim 33, wherein said fixation element comprises a
23 mating feature at its proximal end.
- 24 35. A method as claimed in claim 33, wherein said fixation element comprises a
25 screw.
- 26 36. A method as claimed in claim 34, wherein said fixation element is adapted to
27 mate, position, or align with an element adapted to aid in the depthwise positioning of
28 said fixation element with respect to said articular surface.

1 37. A method as claimed in claim 34, wherein said mating feature is adapted to mate,
2 position, or align with the distal portion of an implant.

3 38. A method as claimed in claim 37, wherein said mating feature is adapted to
4 prevent movement of said implant with respect to said fixation element.

5 39. A method as claimed in claim 33, wherein said fixation element comprises a
6 tapered distal feature and/or aggressive distal threads.

7 40. A method for replacing a portion of an articular surface of bone generally defined
8 by a first and a second curve, said method comprising:

9 establishing an axis generally normal to the portion of an articular surface of bone
10 to be replaced based on a first curve and a second curve of said articular surface;

11 excising only a portion of said articular surface adjacent said axis, thereby
12 creating an implant site;

13 fabricating an artificial implant corresponding to the dimensions of said implant
14 site; and

15 installing said artificial implant into said implant site.

16 41. A method as claimed in claim 40, wherein said implant comprises a bone-facing
17 distal surface adapted to mate with said implant site, said surface comprising at least one
18 mating feature; and a proximal surface having a contour substantially matching or based
19 on the original surface contour of said excised portion of said articular surface.

20 42. A method as claimed in claim 41, wherein said mating feature is selected from the
21 group consisting of: barbs, threads, ribs, fins, milled slots, tapered distal features, features
22 to prevent rotational movement of said implant, or features to increase friction between
23 said implant and the aperture at said implant site.

24 43. A method for replacing a portion of an articular surface of bone generally defined
25 by a first and a second curve, said method comprising:

26 establishing an axis generally normal to the portion of an articular surface of bone
27 to be replaced based on a first curve and a second curve of said articular surface;

28 excising only a portion of said articular surface adjacent said axis, thereby
29 creating an implant site;

- 1 selecting from a set of variously-sized artificial implants an artificial implant
2 corresponding to the dimensions of said implant site; and
3 installing said selected implant into said implant site.
- 4 44. A method as claimed in claim 43, wherein said first and second curves are
5 anterior-posterior (AP) and medial-lateral (ML) curves.
- 6 45. A method as claimed in claim 43, wherein said excising step is performed by
7 cutting at least a portion of said articular surface radially symmetrically about said axis.
- 8 46. A method as claimed in claim 43, wherein said implant comprises a bone-facing
9 distal surface adapted to mate with said implant site, said surface comprising at least one
10 mating feature; and a proximal surface having a contour substantially matching or based
11 on the original surface contour of said excised portion of said articular surface.
- 12 47. A method as claimed in claim 46, wherein said mating feature is selected from the
13 group consisting of: barbs, threads, ribs, fins, milled slots, tapered distal features, features
14 to prevent rotational movement of said implant, or features to increase friction between
15 said implant and the aperture at said implant site.
- 16 48. A method as claimed in claim 43, wherein said establishing step is performed
17 using a tool comprising a first element having an aiming feature and a contact surface
18 mounted to a shaft, and a second element with a contact surface movable with respect to
19 the contact surface of the first element, wherein, when said tool is placed on a non-
20 spherical articular surface, both contact surfaces make contact with said articular surface.
- 21 49. A method as claimed in claim 43, wherein said establishing step is performed by
22 installing a guide pin or wire into said articular surface along said axis.
- 23 50. A method as claimed in claim 43, wherein said excising step is performed using a
24 cutting tool that rotates about said axis.
- 25 51. A method as claimed in claim 43, wherein said installing step comprises driving a
26 fixation element into said articular surface along said axis.
- 27 52. A method as claimed in claim 51, wherein said fixation element comprises a
28 mating feature at its proximal end.

- 1 53. A method as claimed in claim 51, wherein said fixation element comprises a
2 screw.
- 3 54. A method as claimed in claim 52, wherein said mating feature is adapted to mate,
4 position, or align with an element adapted to aid in the depthwise positioning of said
5 fixation element with respect to said articular surface.
- 6 55. A method as claimed in claim 52, wherein said mating feature is adapted to mate
7 with the distal portion of an implant.
- 8 56. A method as claimed in claim 55, wherein said mating feature is adapted to
9 prevent movement of said implant with respect to said fixation element.
- 10 57. A method as claimed in claim 51, wherein said fixation element comprises a
11 tapered distal feature and/or aggressive distal threads.
- 12 58. A tool for holding an implant, said tool comprising:
13 at least one element adapted for connection to an activatable suction source; and
14 an elastomeric suction tip adapted to receive an implant, said tip being coupled to
15 said at least one element.
- 16 59. A tool as claimed in claim 58, further comprising a rigid tip disposed within the
17 elastomeric suction tip, whereby a force in the direction of the delivery site of said
18 implant permits said rigid tip to contact said implant while said implant is being held by
19 said suction tip.
- 20 60. A method for holding an implant comprising:
21 coupling a suction source to an implant; and
22 activating said suction source.
- 23 61. A method for delivering an implant comprising:
24 coupling an active suction source to an implant;
25 approximating said implant to its delivery site; and
26 applying a force to said implant in the direction of said delivery site.
- 27 62. A tool for removing an implant from its delivery site, said tool comprising:
28 an element with a generally leading edge and a barb element disposed proximally
29 to the leading edge; and

- 1 at least one structural element that creates sufficient bias of the leading edge of
2 the tool to rigidly couple to a surface of the implant to be removed.
- 3 63. A tool as claimed in claim 62, further comprising means for coupling said tool to
4 a slap hammer or slide hammer capable of applying a pulling force to an implant held at
5 said barb element.
- 6 64. A tool for removing an implant from its delivery site, said tool comprising:
7 a cylindrical structure having an end; said end comprising a longitudinal central
8 axis, a circular blade portion having a leading edge comprising a blade surface turned on
9 the distal-most portion, and a lip portion disposed proximally with respect to the leading
10 edge; and
11 a plurality of slits parallel to the longitudinal central axis of said end formed along
12 the length of said cylindrical structure, so as to permit sufficient outward expansion of the
13 distal end to accommodate the top edge of an implant therein.
- 14 65. A tool as claimed in claim 64, further comprising means for coupling said tool to
15 a slap hammer or slide hammer capable of applying a pulling force to an implant held in
16 said distal end.
- 17 66. A method for removing an implant from its delivery site, said method comprising:
18 disposing the lip portion of the leading edge of the end of a removal tool over the
19 upper edge of an implant seated in its delivery site; and
20 applying a pulling force to said removal tool.
- 21 67. A method as claimed in claim 66, wherein said pulling force is applied using a
22 slap hammer or slide hammer.
- 23 68. A device for measuring a portion of an articular surface of bone, said device
24 comprising:
25 a handpiece;
26 a shaft disposed within said handpiece, said shaft comprising a feature for
27 aligning with a working axis or mating to a fixed element;
28 a contact tip moveably coupled to said shaft; and
29 at least one measuring element coupled to said contact tip or said shaft.

- 1 69. A device as claimed in claim 68, further comprising recording means for
2 recording measurements taken by said at least one measuring element.
- 3 70. A device as claimed in claim 69, wherein translation and/or rotation of the contact
4 tip with respect to the handpiece or shaft causes said at least one measuring element to
5 measure travel of the contact tip, and the recording means to record at least one
6 measurement taken by at least one said measuring element.
- 7 71. A device as claimed in claim 70, further comprising machine-readable code to
8 analyze said at least one recorded measurement and output to a user the dimensions of an
9 implant to be used in said articular surface.
- 10 72. A device as claimed in claim 70, further comprising machine-readable code to
11 analyze said at least one recorded measurement and compare said measurement to at least
12 one previously taken measurement.
- 13 73. A device as claimed in claim 70, further comprising machine-readable code to
14 analyze said at least one recorded measurement, select an implant corresponding to said
15 at least one measurement from a set of variously-sized implants, and output to a user said
16 selection.
- 17 74. A device for mapping a portion of an articular surface of bone, said device
18 comprising:
19 a handpiece;
20 an inner shaft running along the length of and disposed within said handpiece,
21 said inner shaft comprising a mating feature for mating with a fixed element located
22 substantially normal with respect to an articular surface;
23 a contact tip slidably and rotatably disposed about said inner shaft;
24 a rotary measuring element coupled to and rotating with said contact tip; and
25 a linear measuring element nested concentrically and coaxially to said rotary
26 measuring element, and coupled to and moving linearly with said contact tip.
- 27 75. A device as claimed in claim 74, further comprising recording means for
28 recording measurements taken by said measuring elements.

- 1 76. A device as claimed in claim 75, wherein translation and/or rotation of the contact
2 tip with respect to the handpiece or shaft causes said measuring elements to measure
3 travel of the contact tip, and the recording means records measurements taken by the
4 measuring elements simultaneously, when the mating feature of said inner shaft is mated
5 with said fixed element and/or said contact tip is fixably aligned to a working axis.
- 6 77. A device as claimed in claim 76, further comprising machine-readable code to
7 analyze said recorded measurements and output to a user the dimensions of an implant to
8 be used in said articular surface.
- 9 78. A device as claimed in claim 76, further comprising machine-readable code to
10 analyze said recorded measurements, select an implant corresponding to said
11 measurements from a set of variously-sized implants, and output to a user said selection.
- 12 79. A set of guide devices for locating a working axis substantially normal with
13 respect to an articular surface of bone or for determining the dimension of an implant to
14 be installed in an articular surface of bone, said set comprising:
15 a plurality of variously dimensioned guide devices, each said guide device having
16 a handling tab or shaft and a contact surface; said contact surface comprising a plurality
17 of points radially extending from said handling tab or shaft; wherein, when at least one
18 said guide device is placed on an articular surface, said contact surface makes contact
19 with said articular surface, and said plurality of points of said contact surface surrounds a
20 defect in said articular surface.
- 21 80. A set of guide devices as claimed in claim 79, wherein said plurality of points of
22 at least one said guide device do not all lie in the same plane.

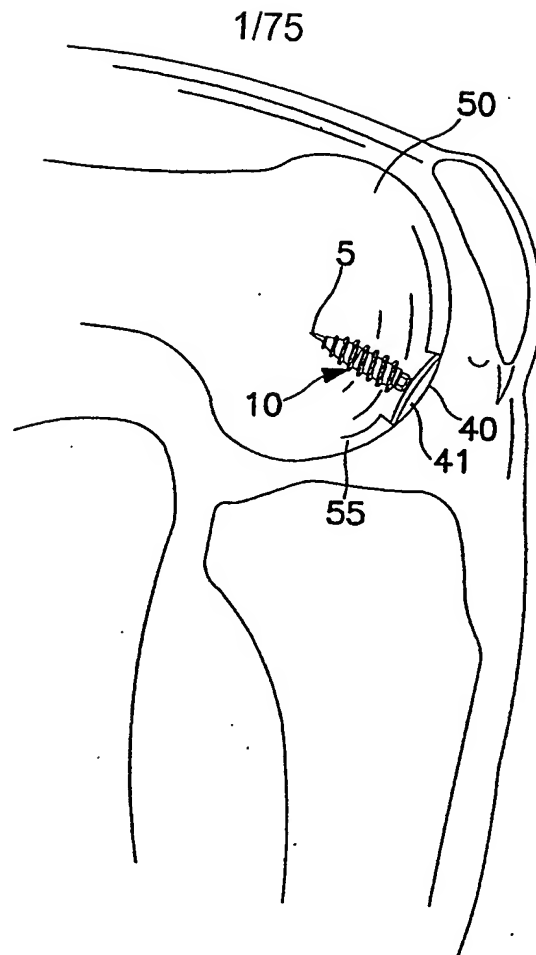


FIG. 1

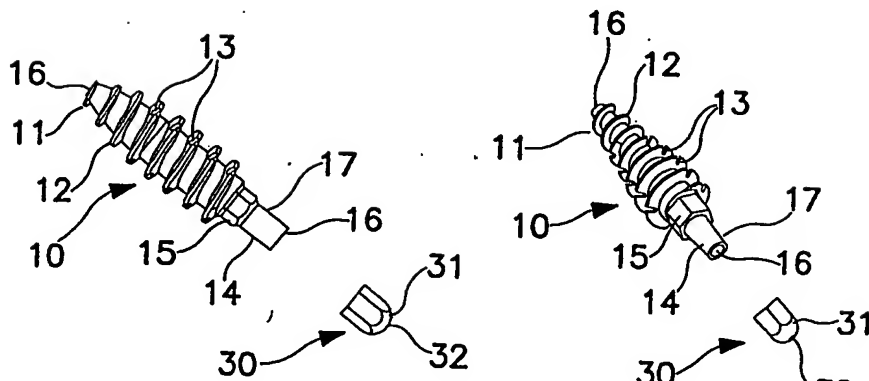


FIG. 2a

FIG. 2b

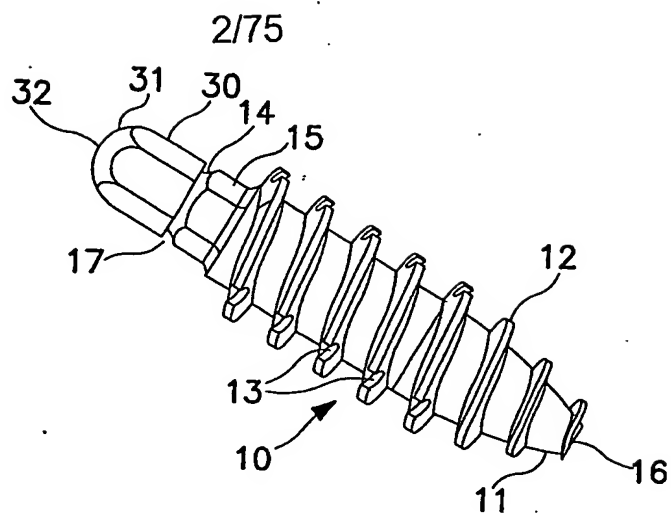


FIG. 3a

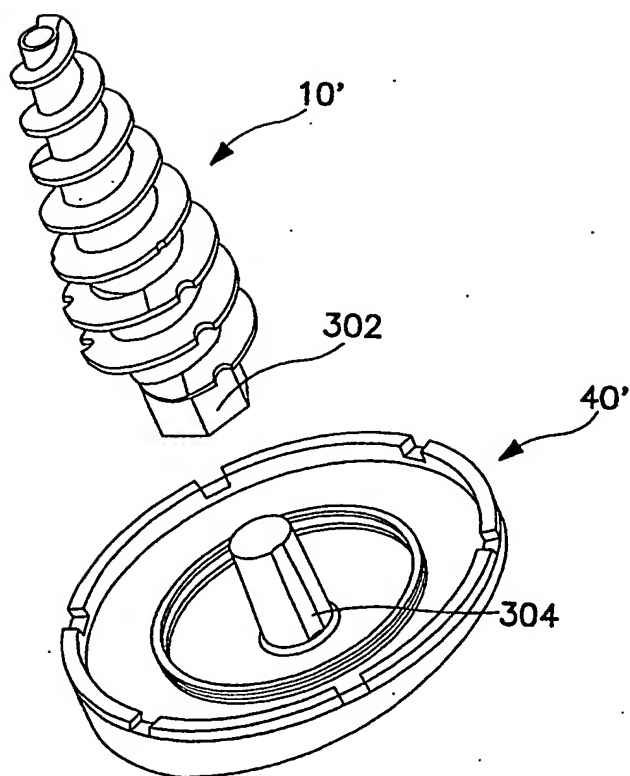


FIG. 3b

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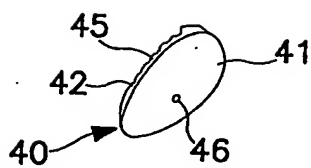


FIG. 4a

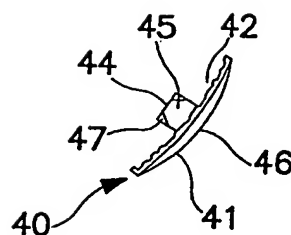


FIG. 4b

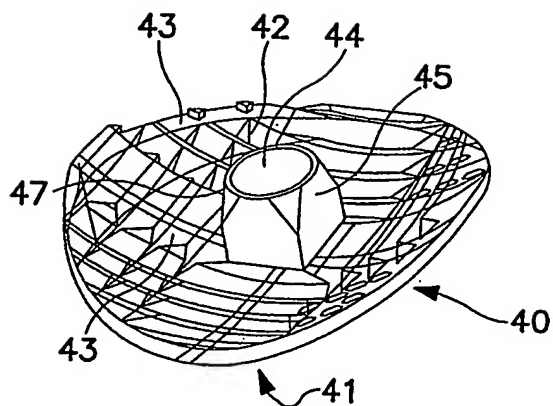


FIG. 4c

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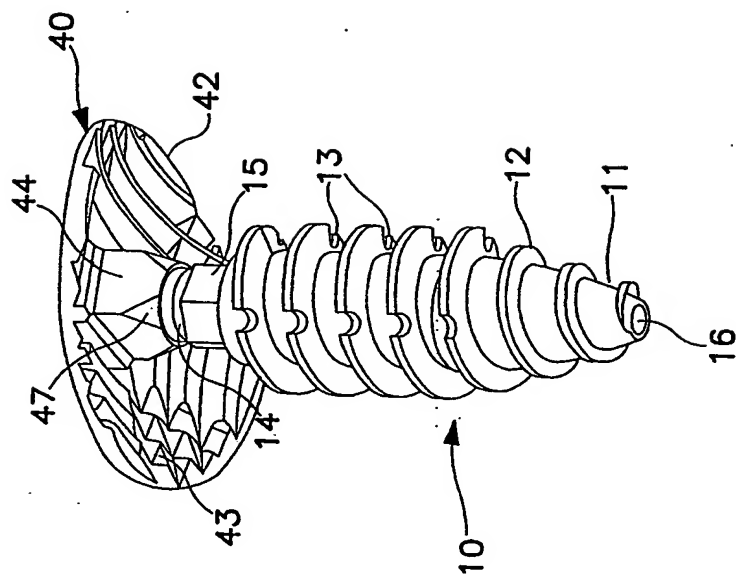


FIG. 5b

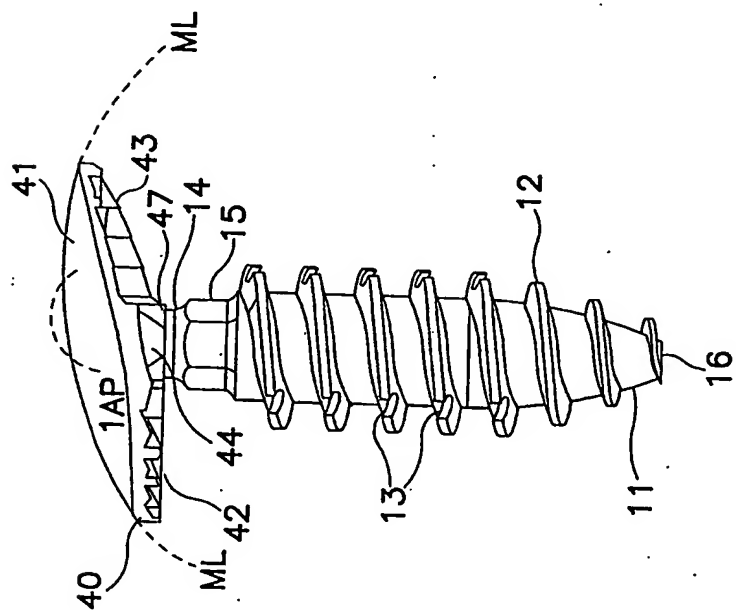


FIG. 5a

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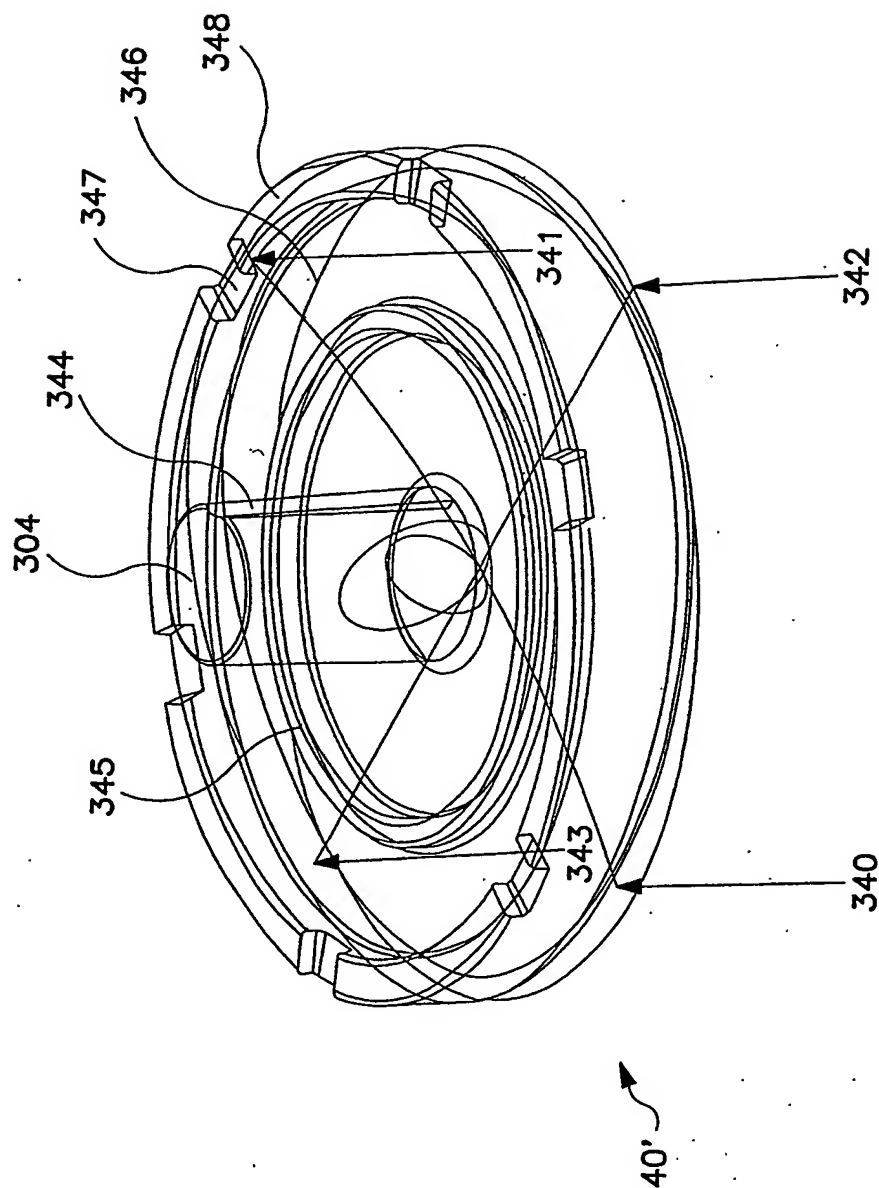


FIG. 5c

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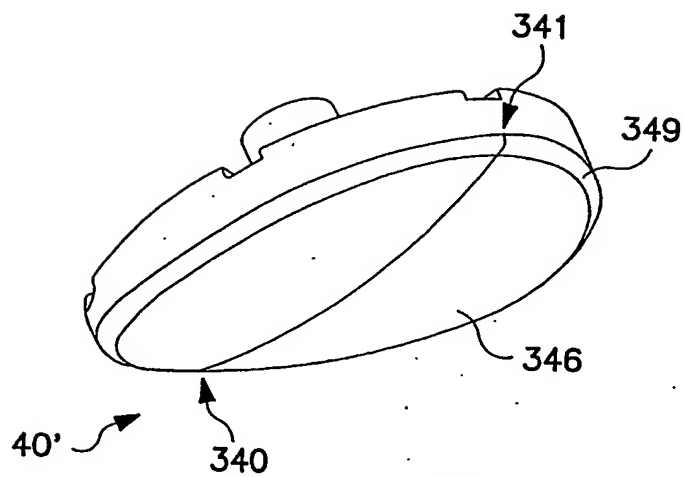
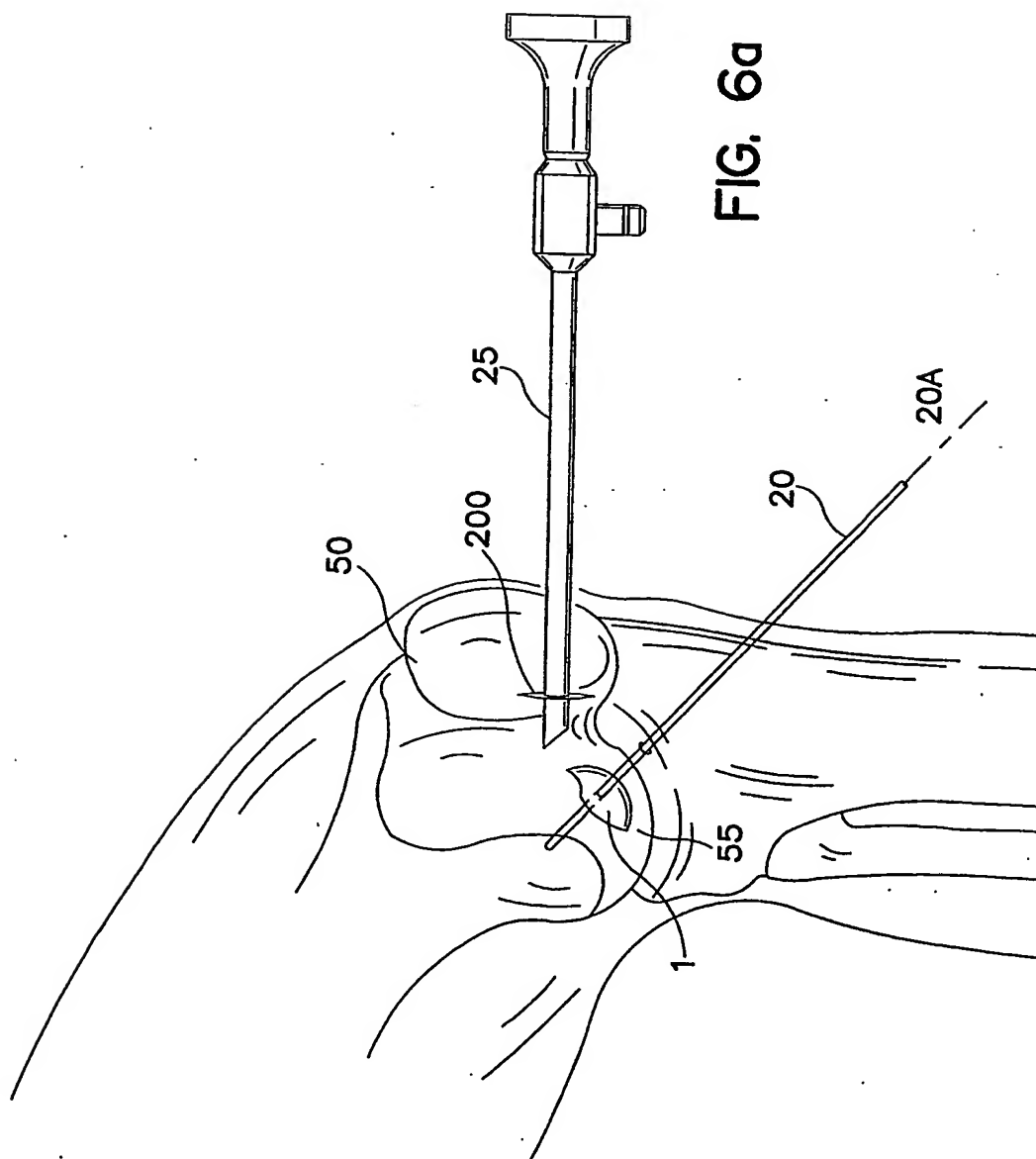
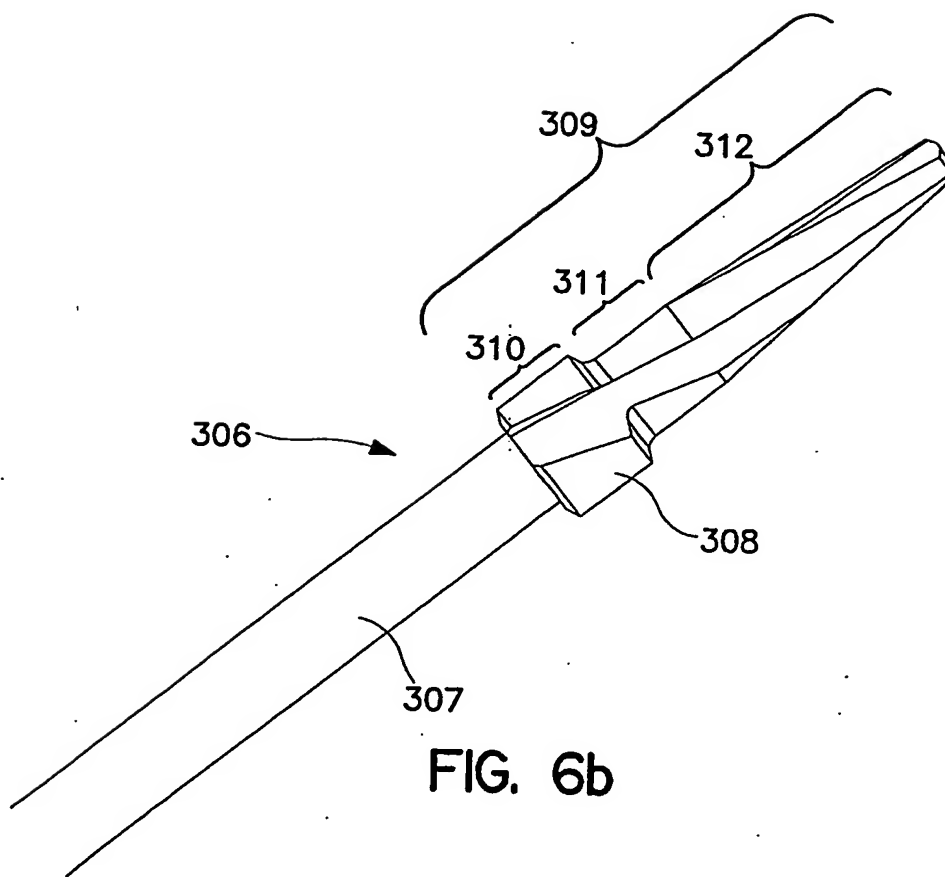


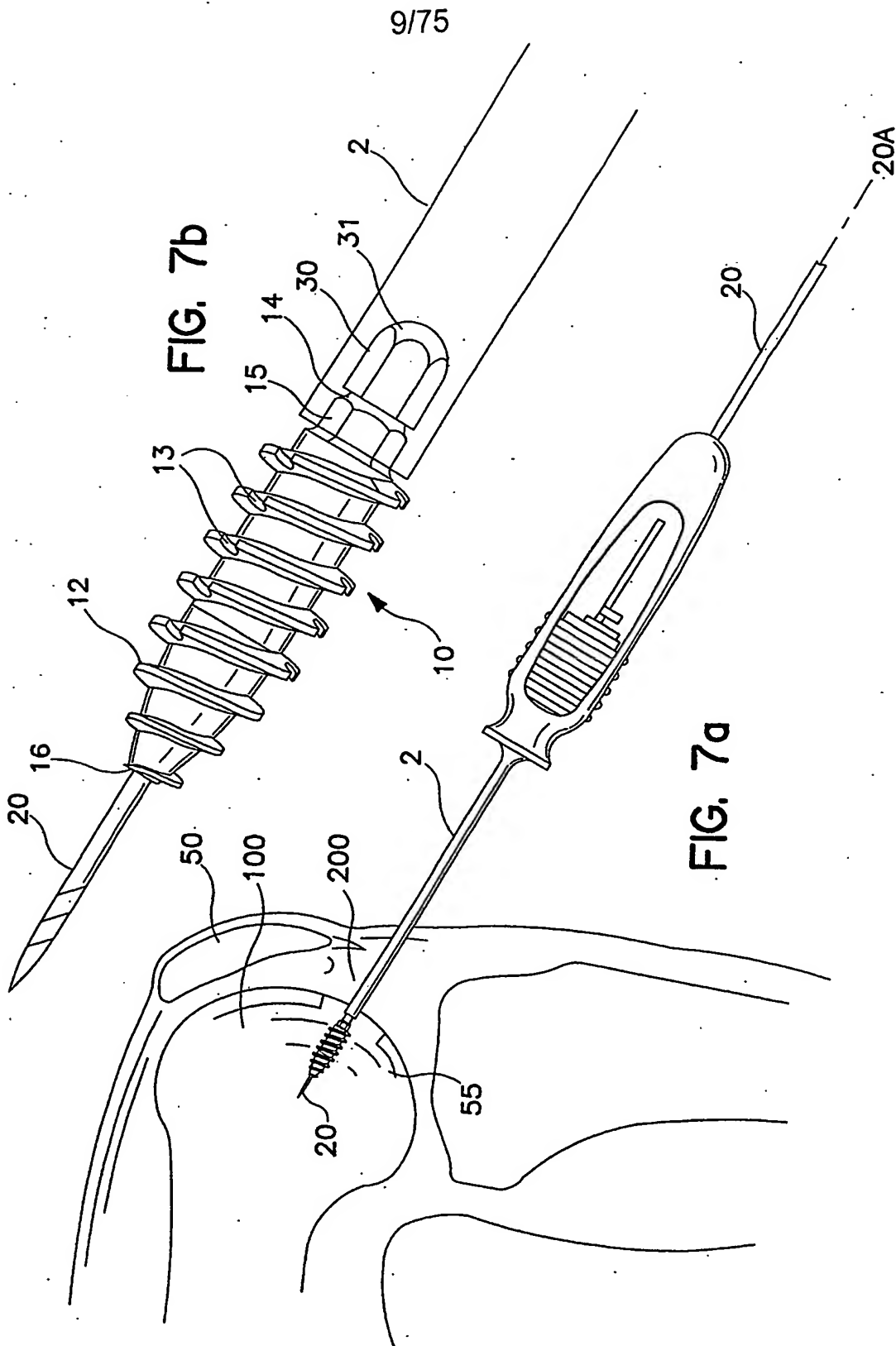
FIG. 5d

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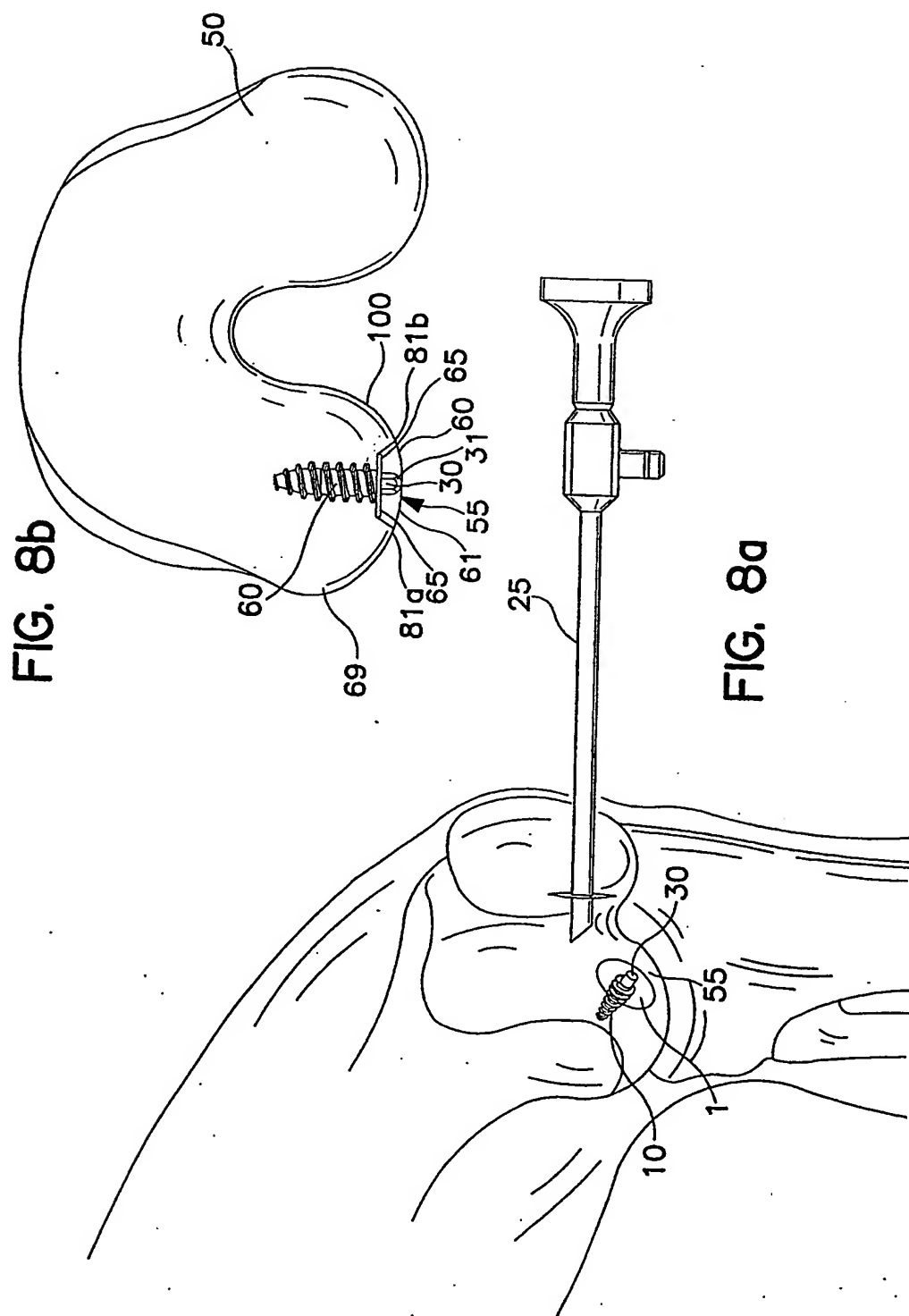


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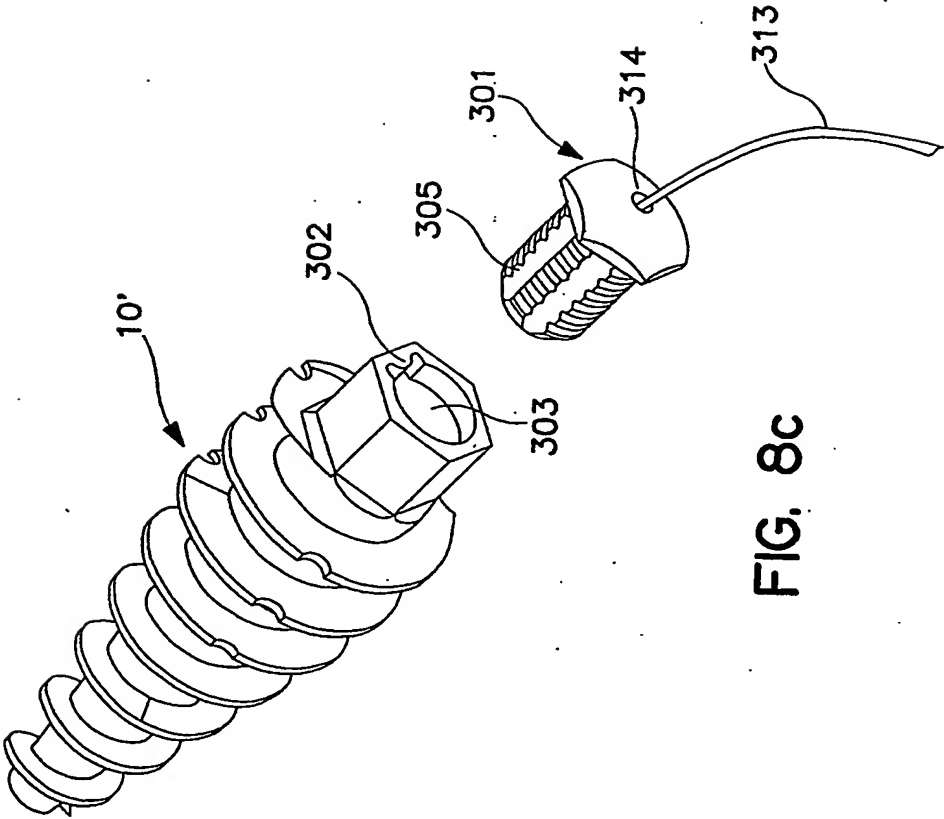
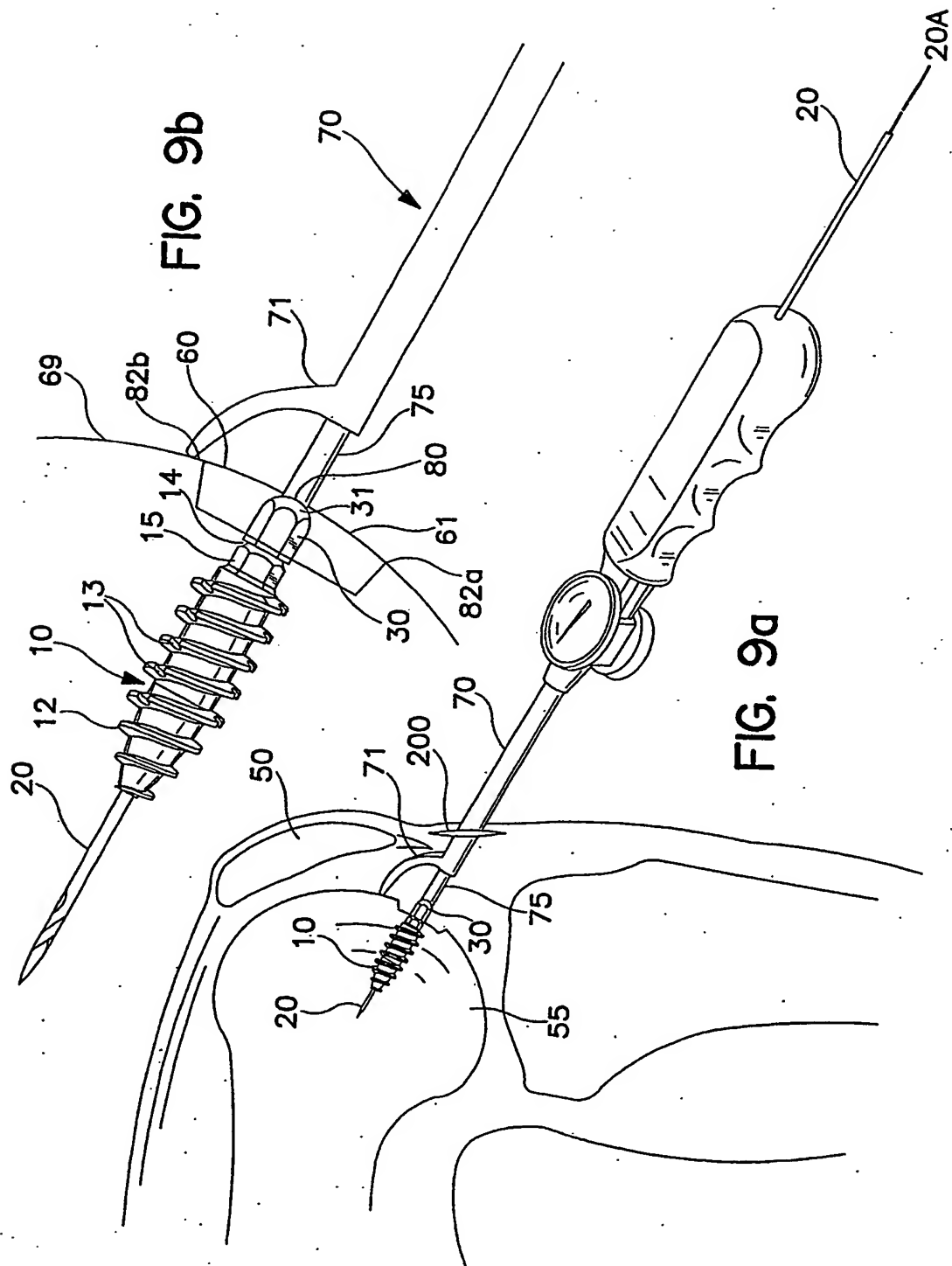


FIG. 8c

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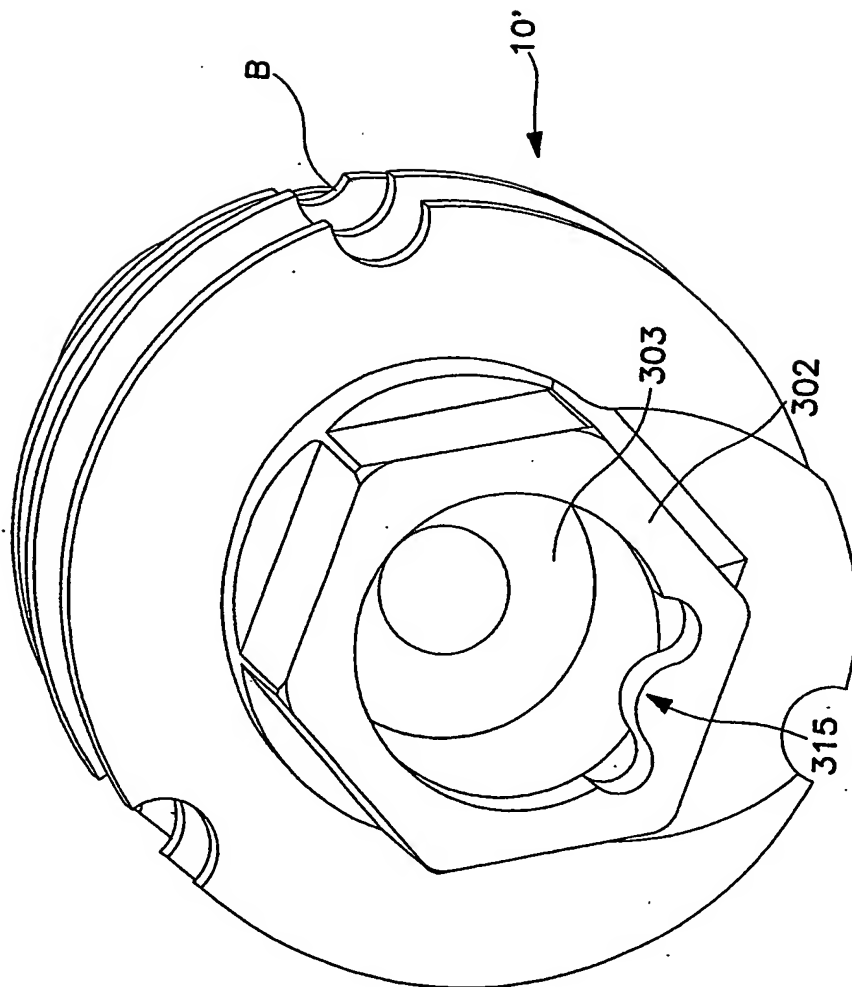
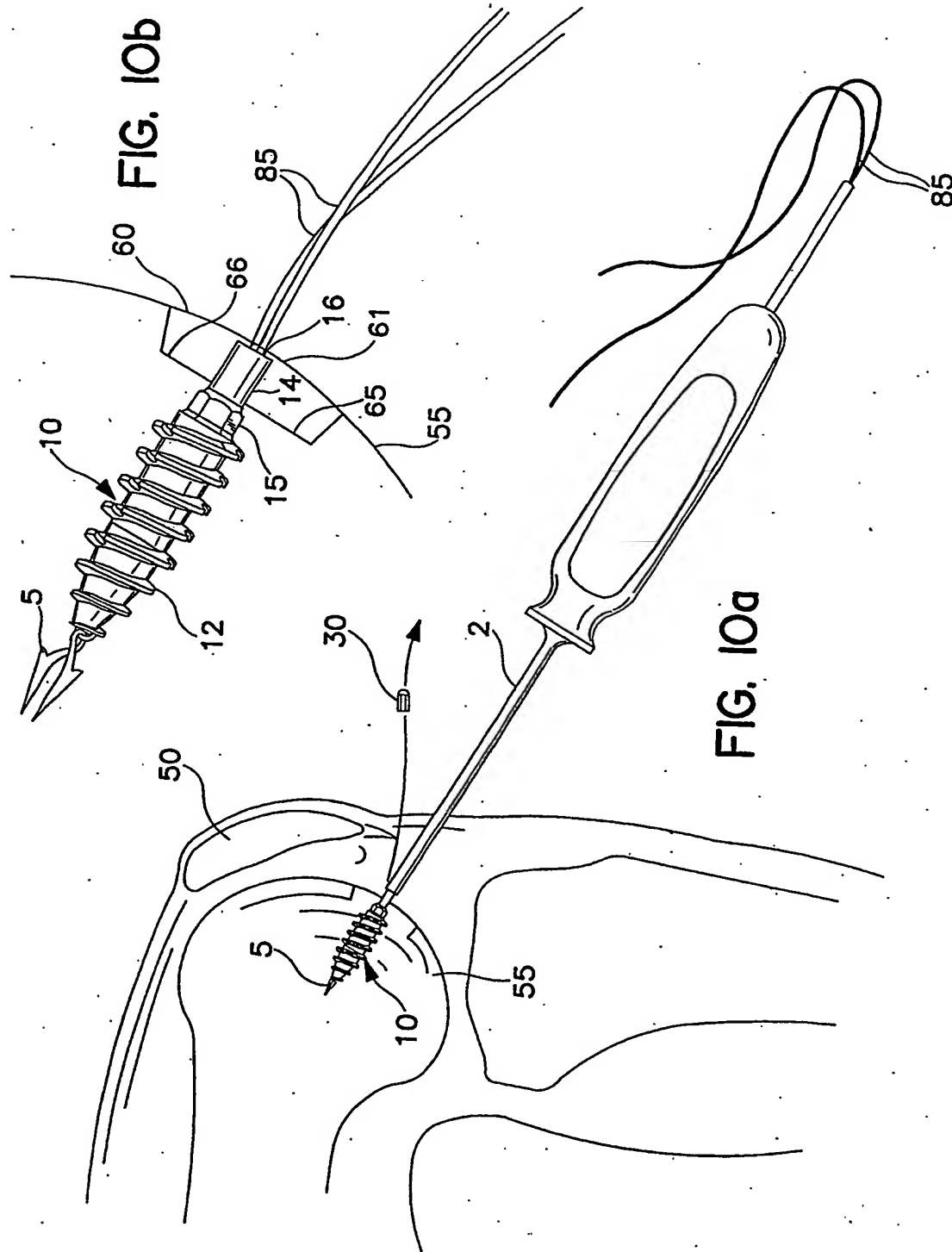
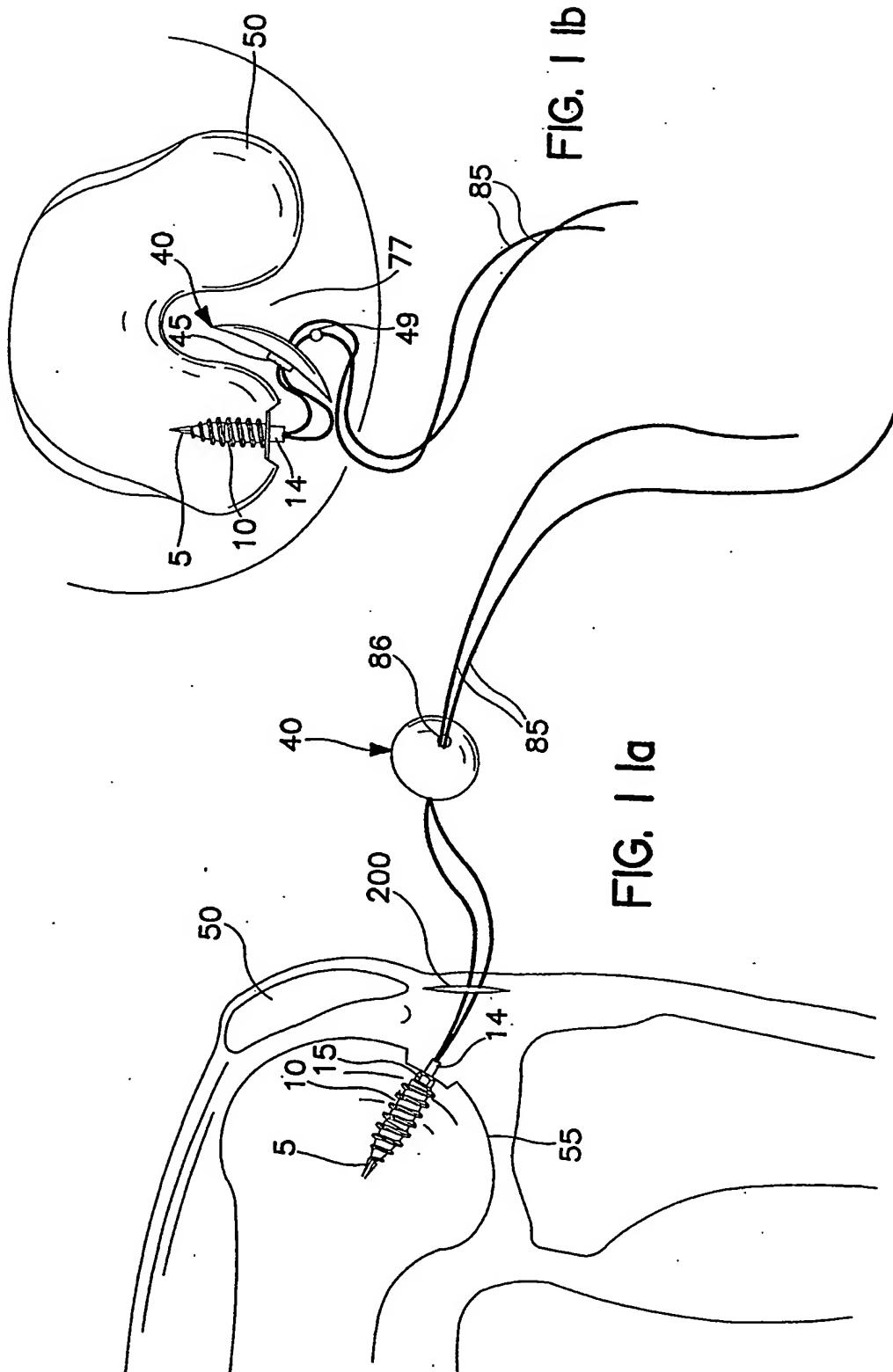


FIG. 9c

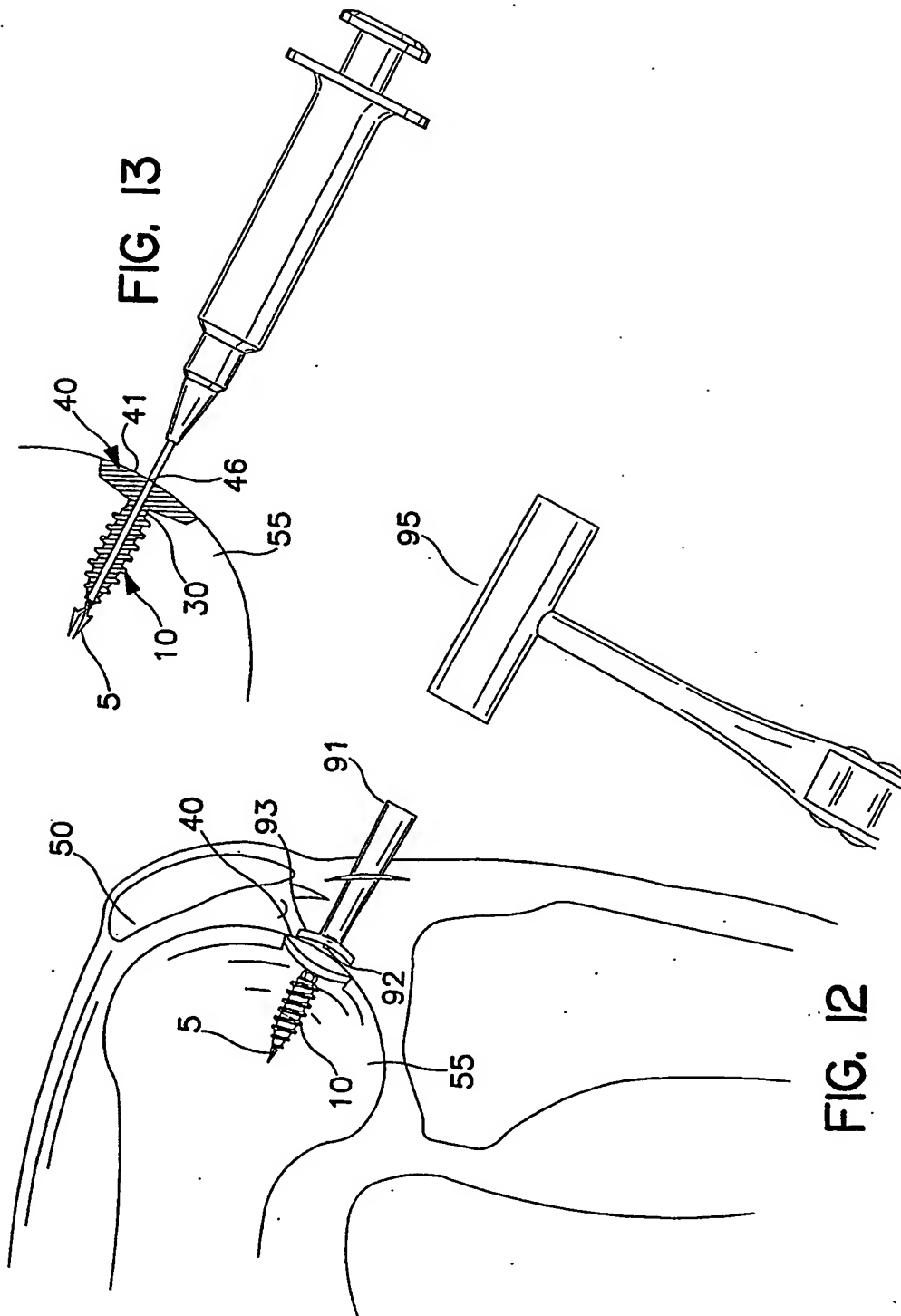
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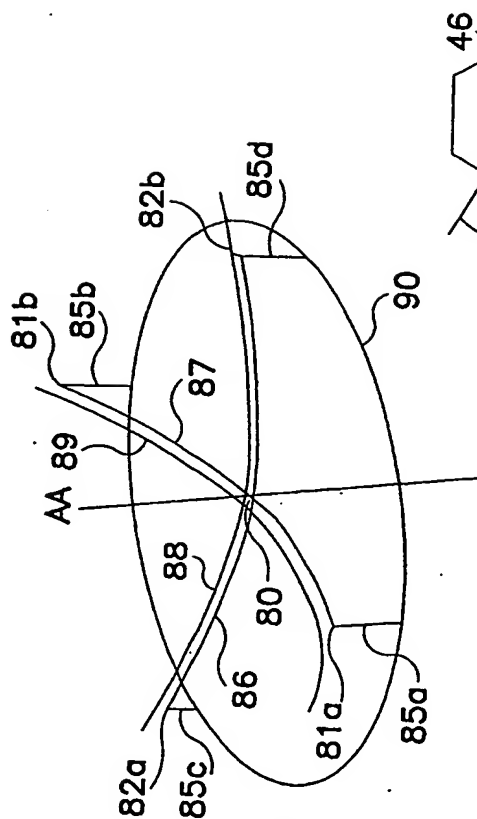


FIG. 14a

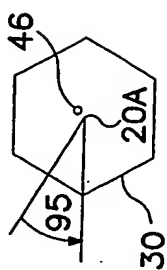


FIG. 14b

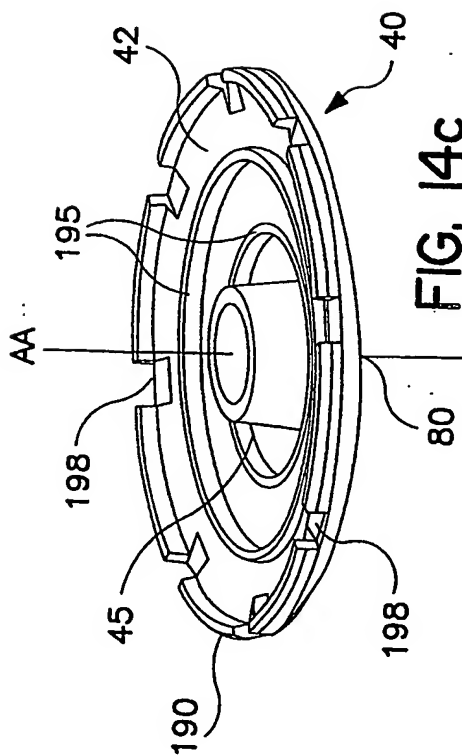
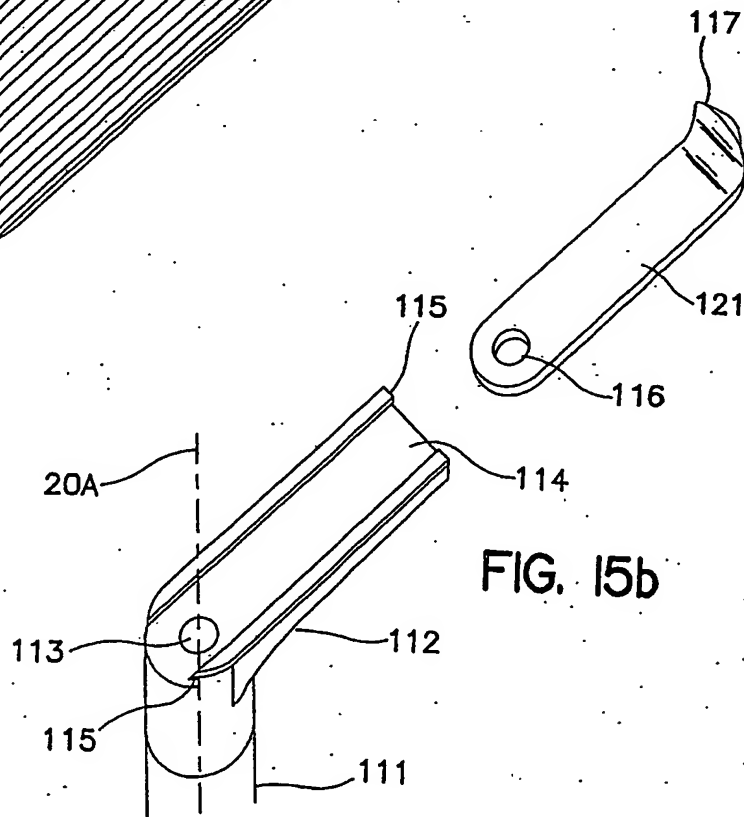
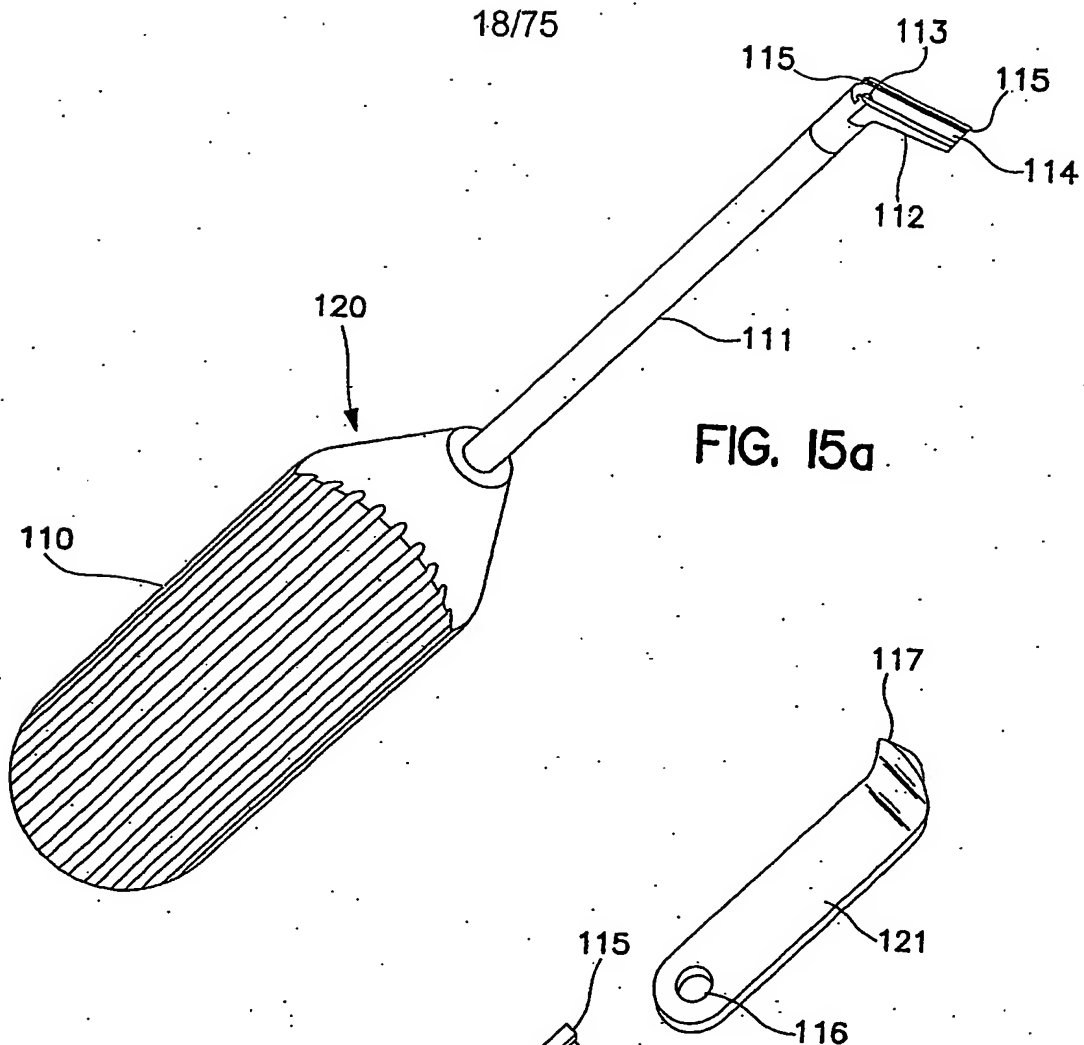
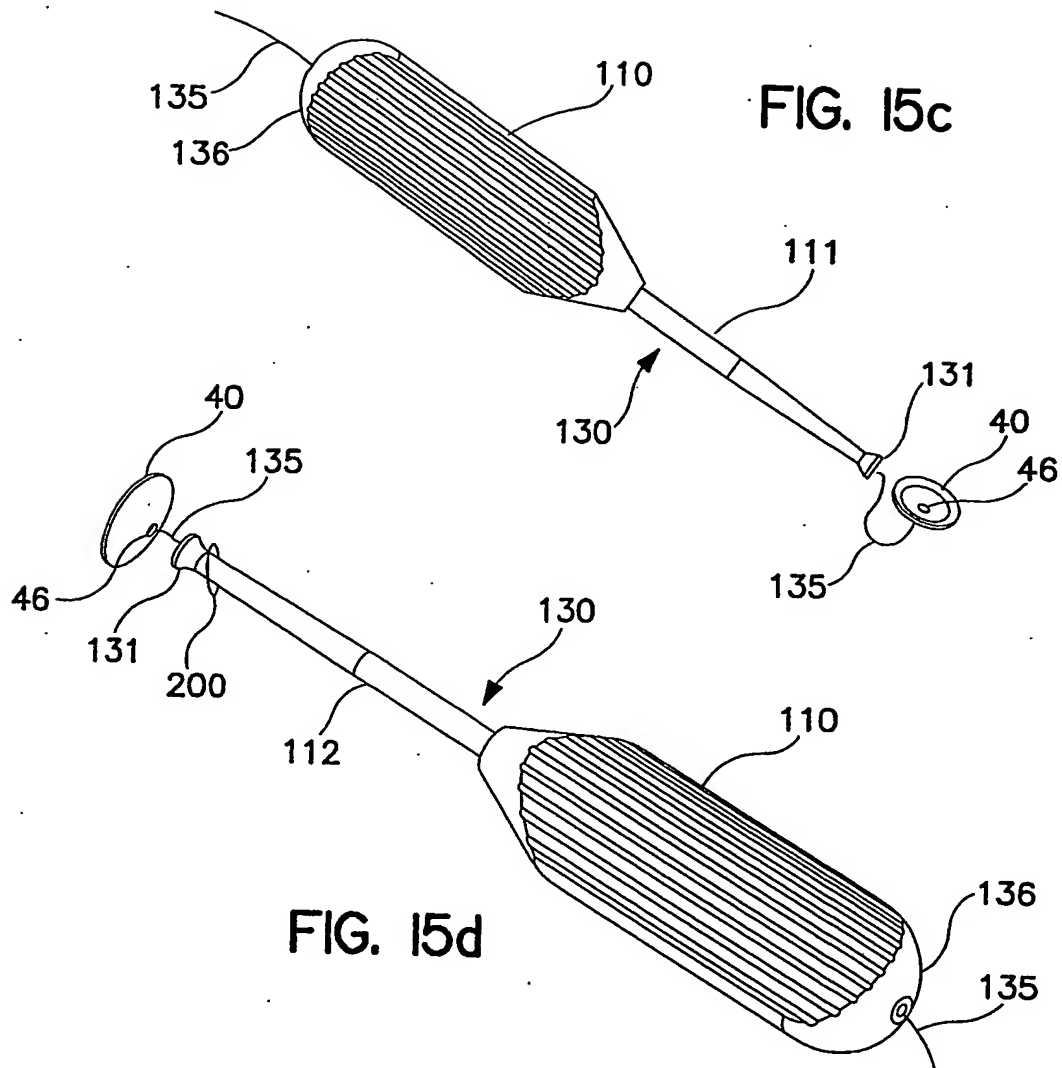


FIG. 14c



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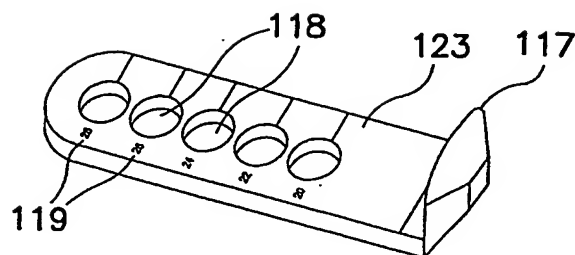


FIG. 17a

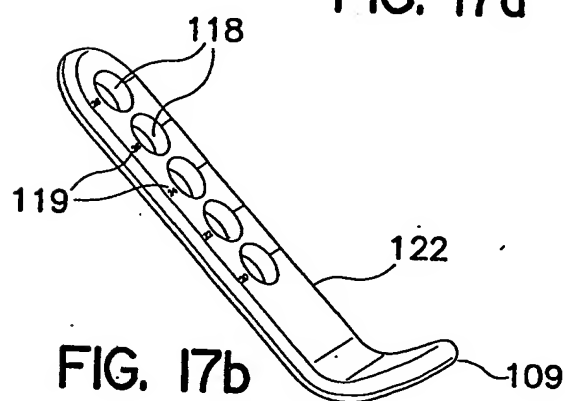


FIG. 17b

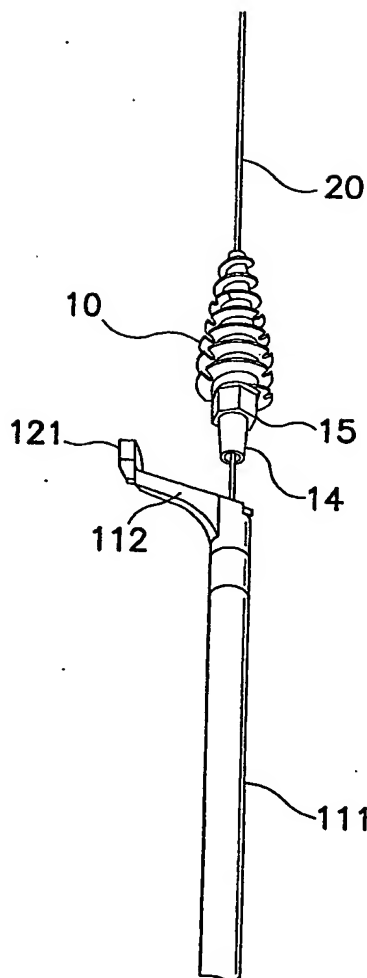


FIG. 16

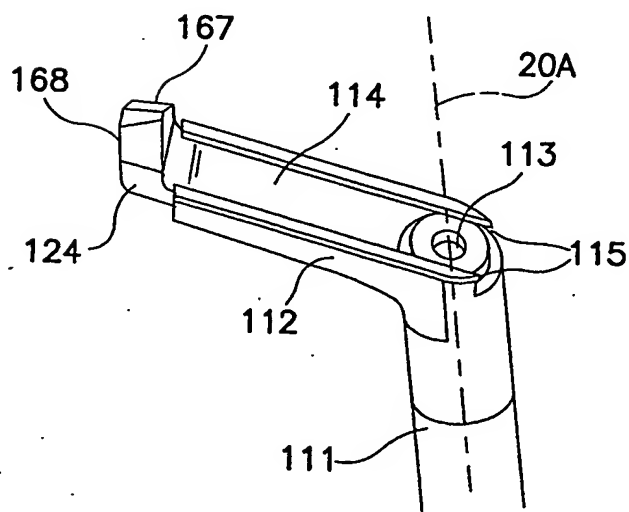


FIG. 17c

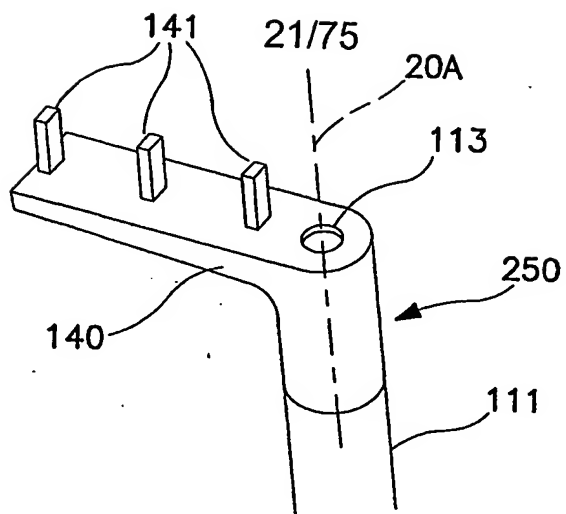


FIG. 18a

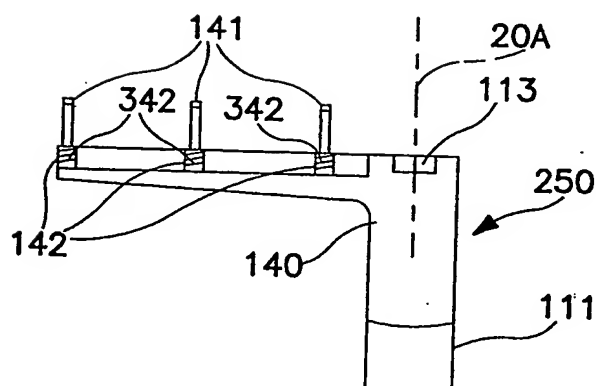


FIG. 18b

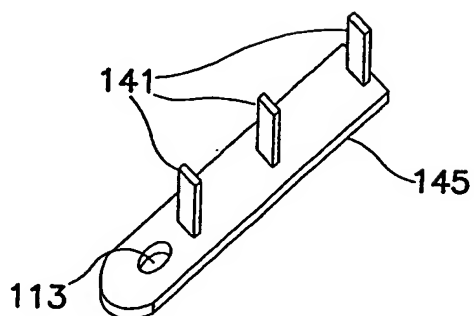


FIG. 18c

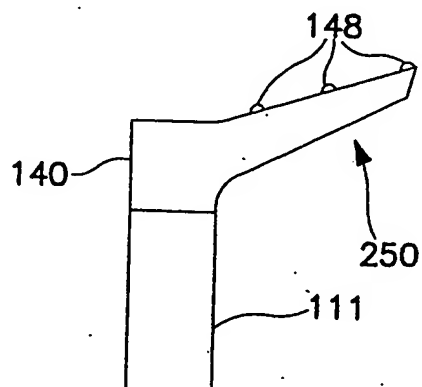


FIG. 18d

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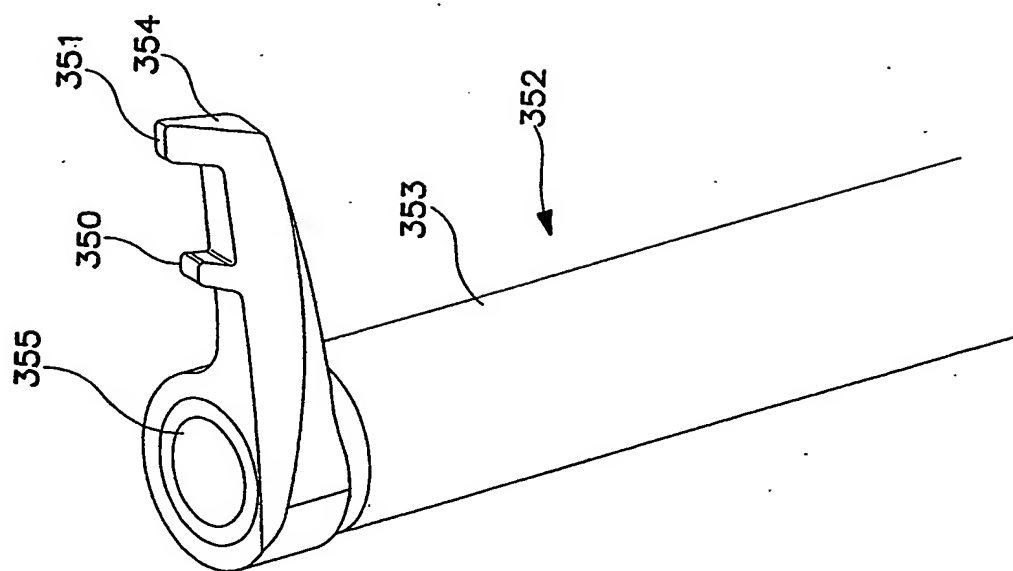
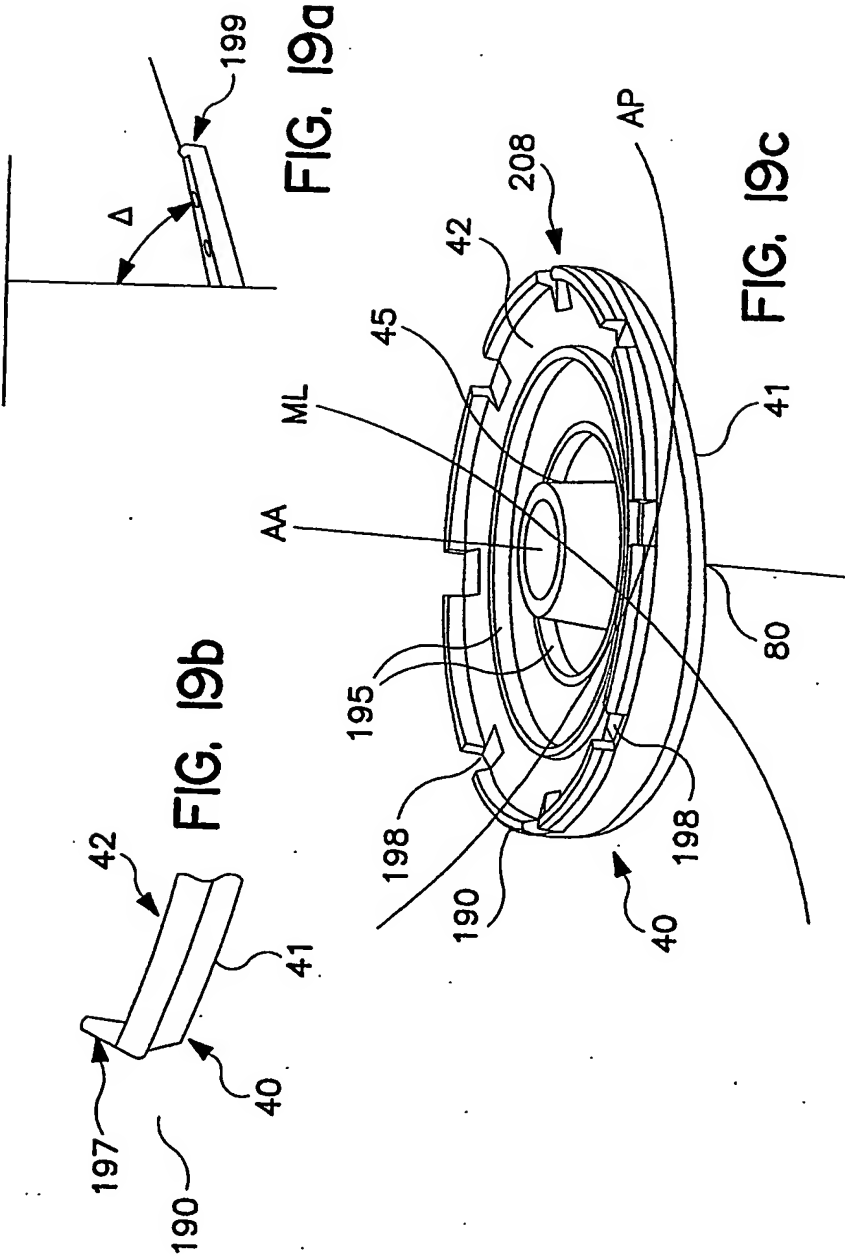


FIG. 18e



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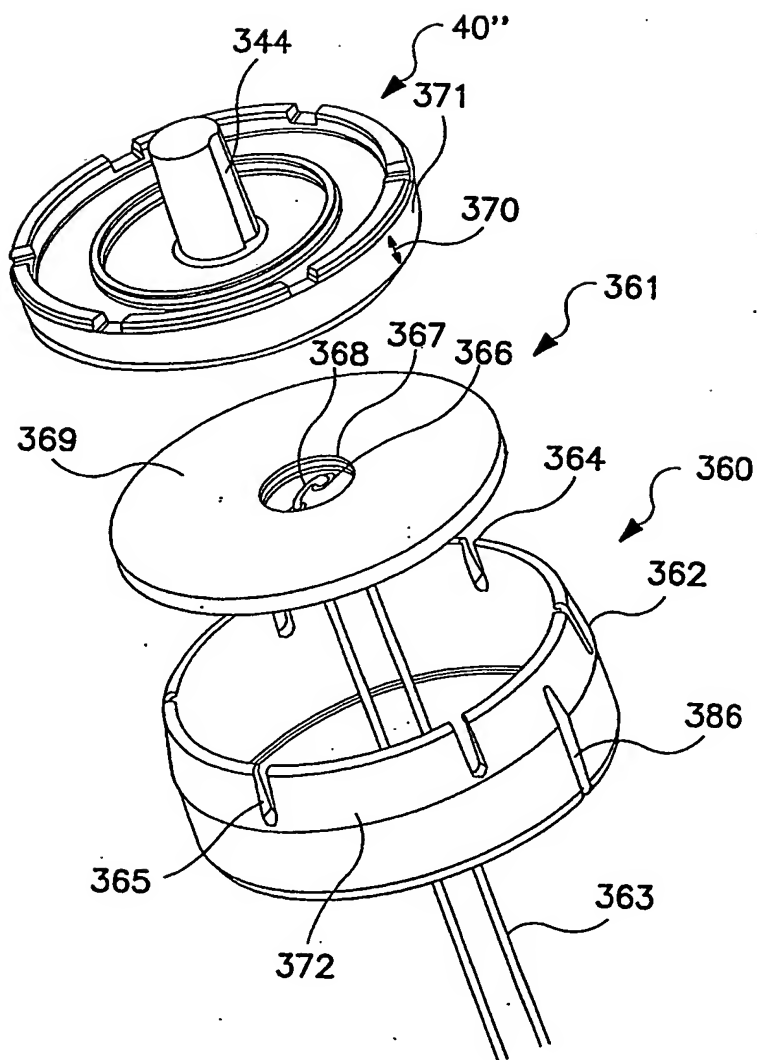


FIG. 19d

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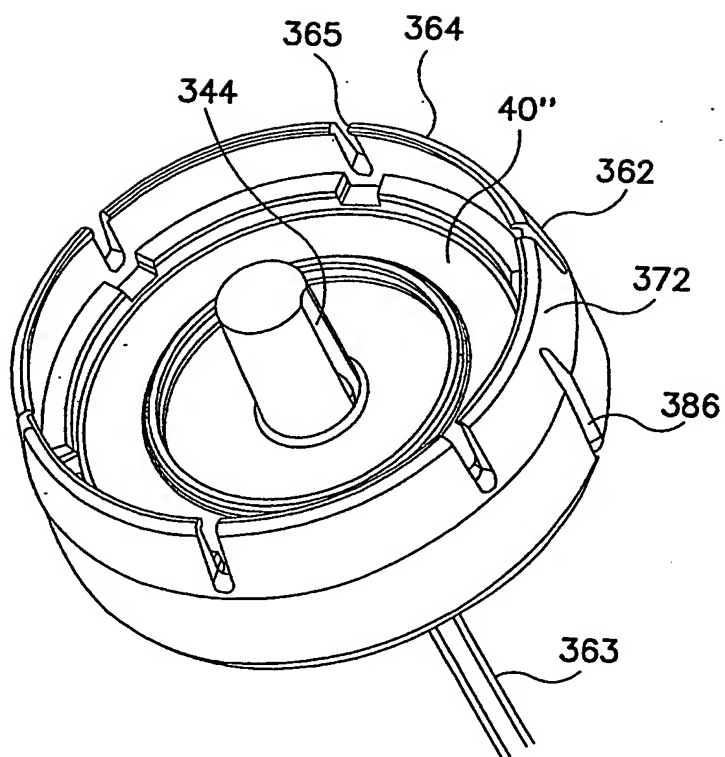


FIG. 19e

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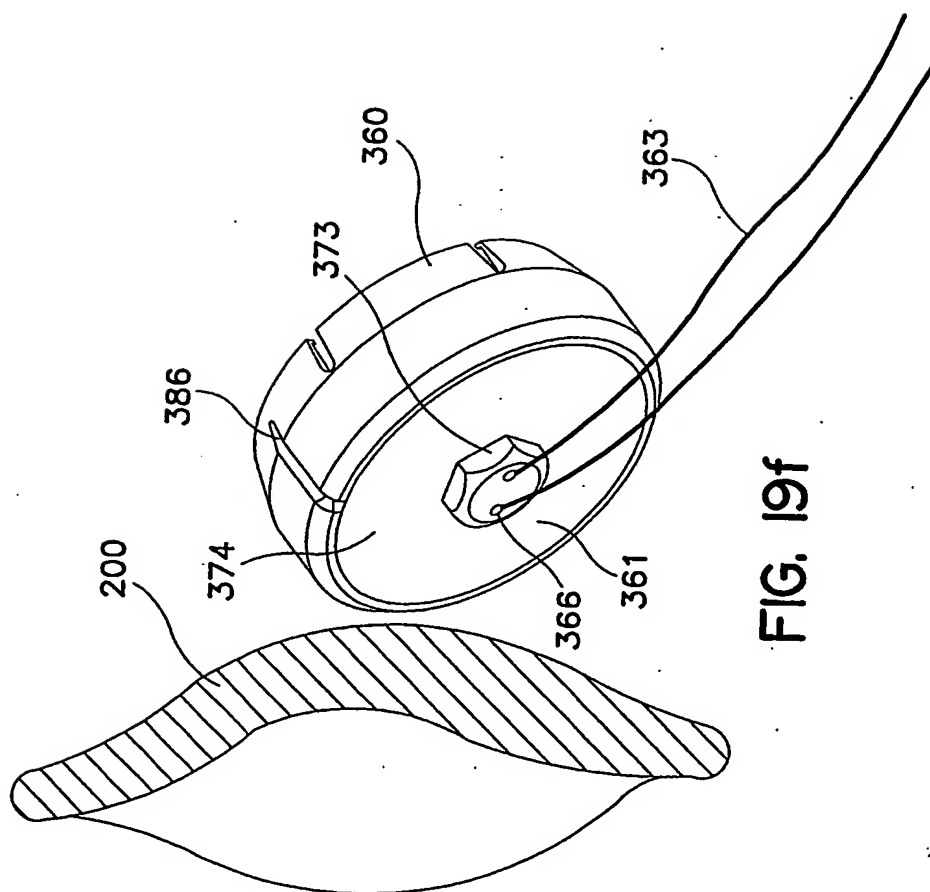
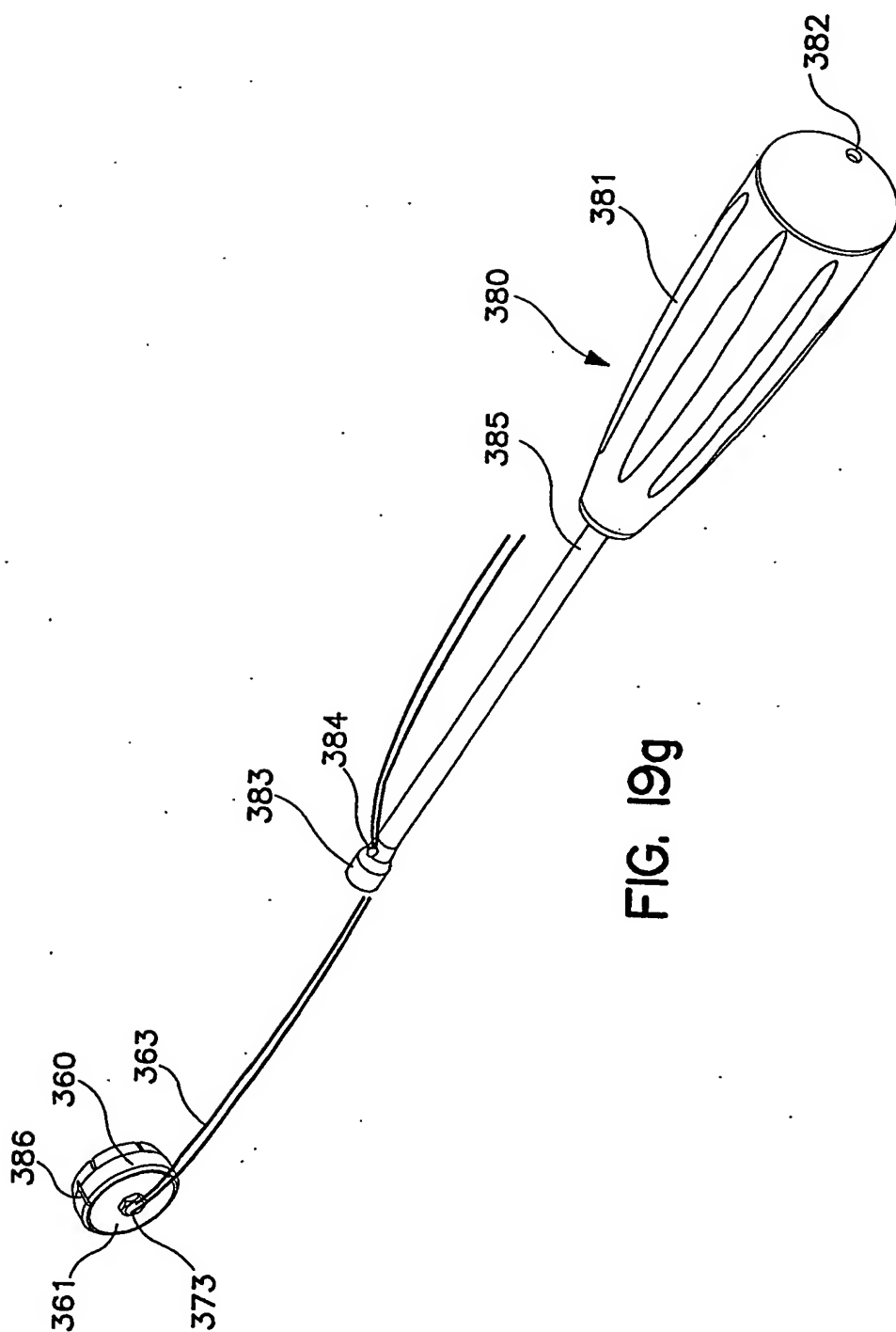
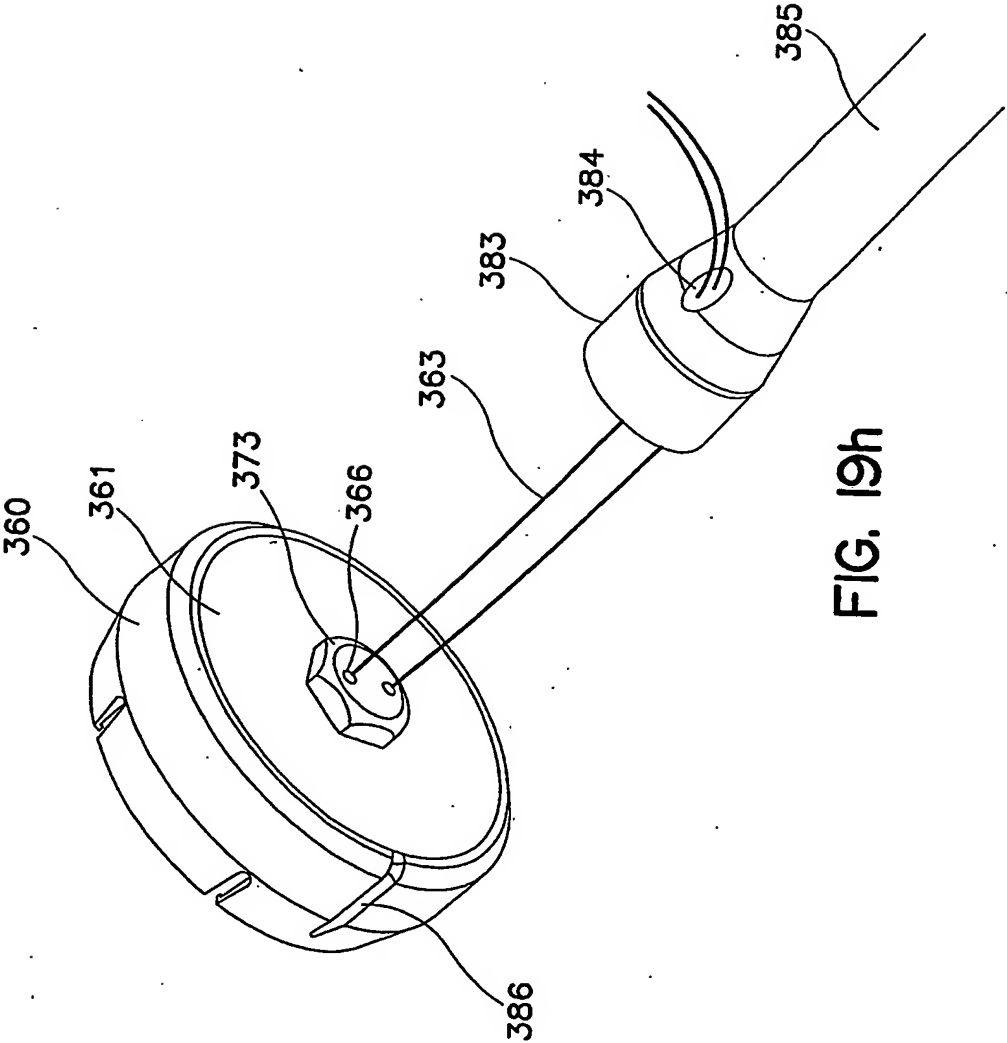


FIG. 19f

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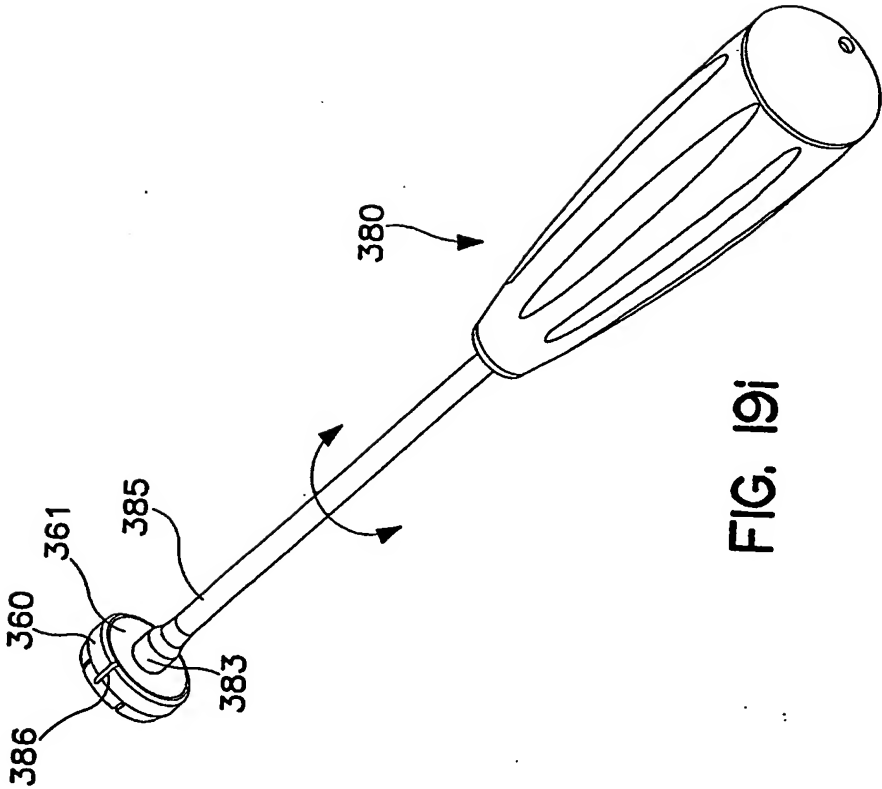


FIG. 19i

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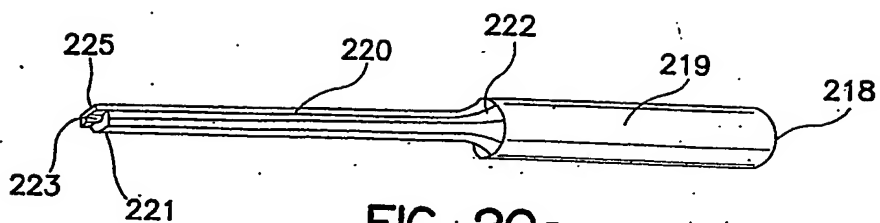


FIG. 20a

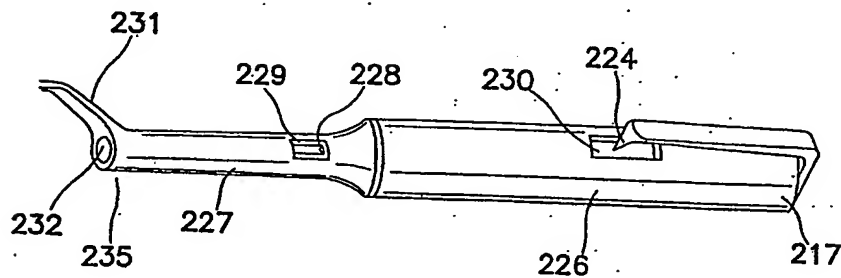


FIG. 20b

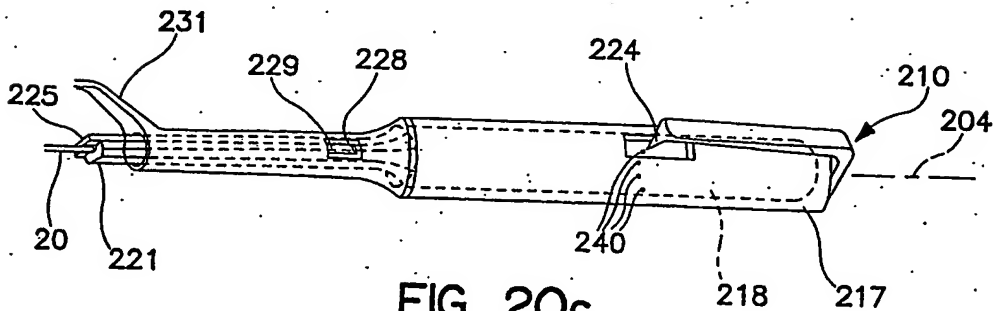


FIG. 20c

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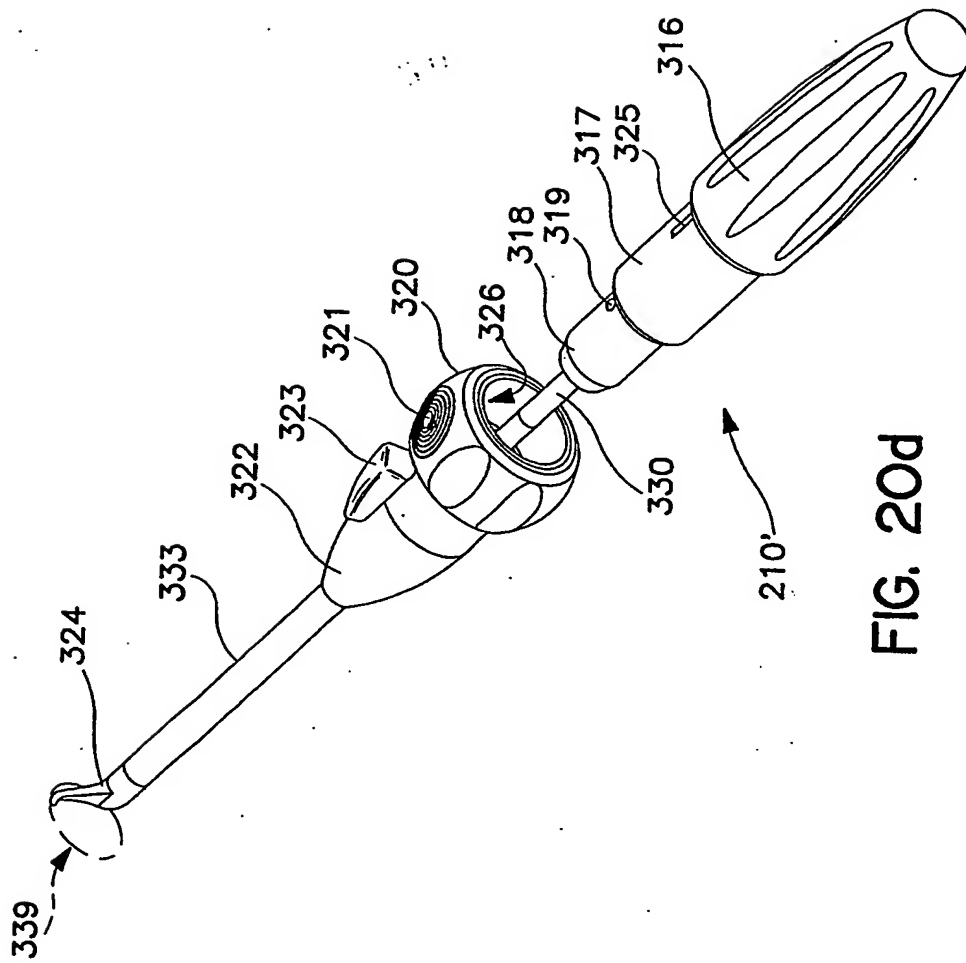


FIG. 20d

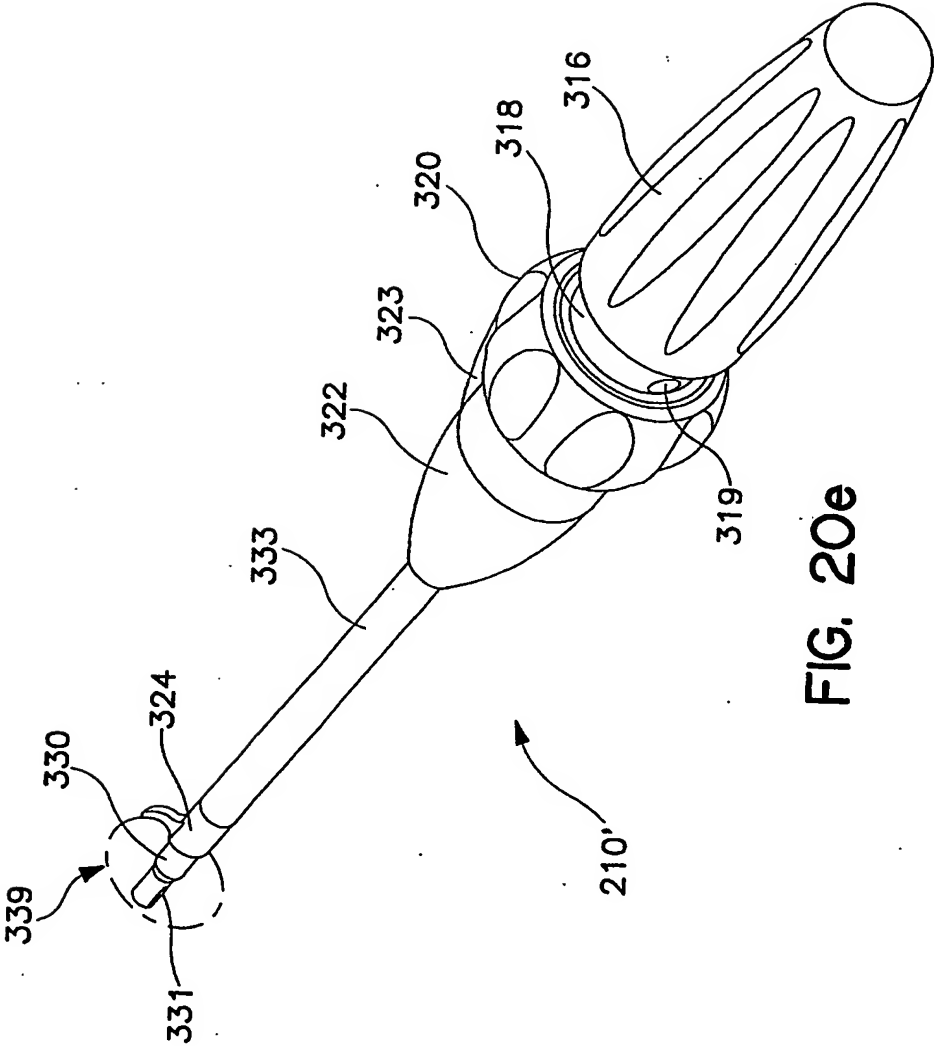


FIG. 20e

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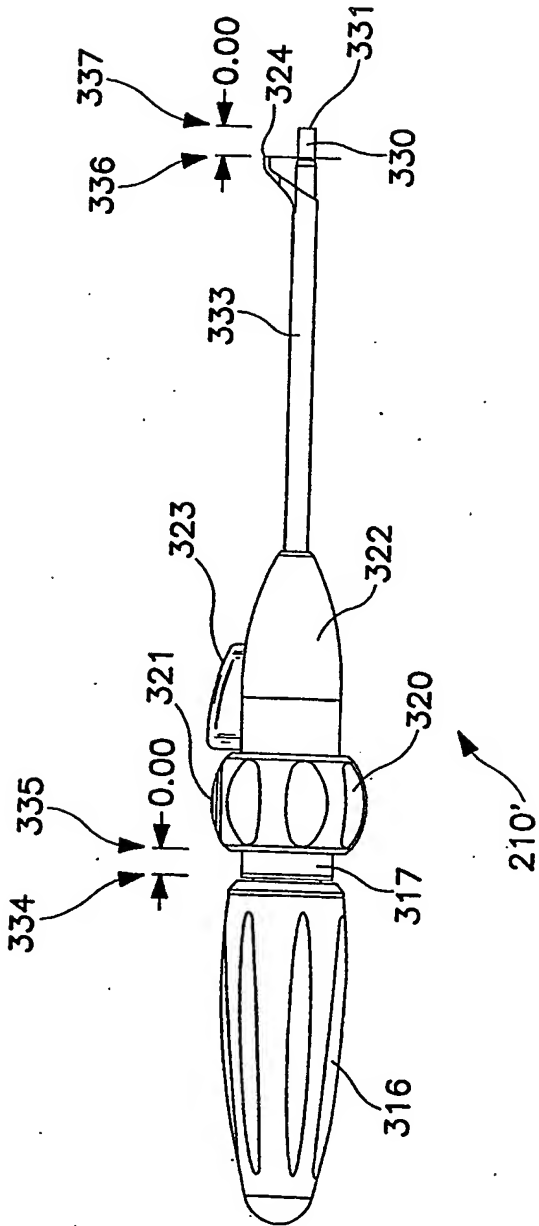


FIG. 20f

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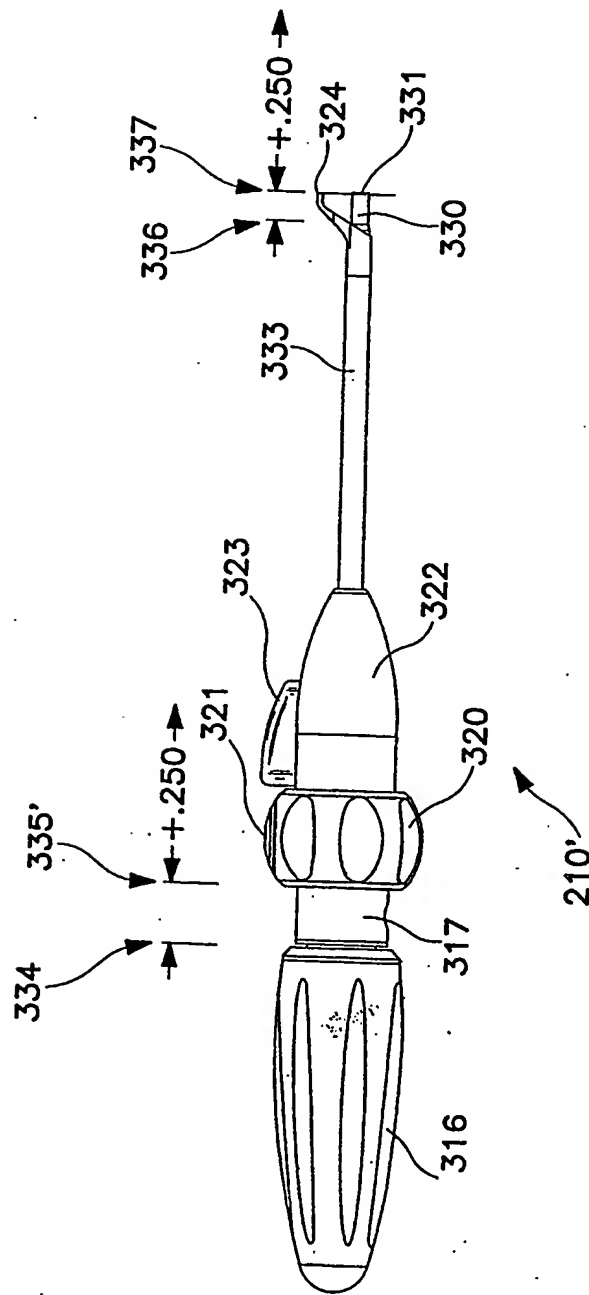


FIG. 20g

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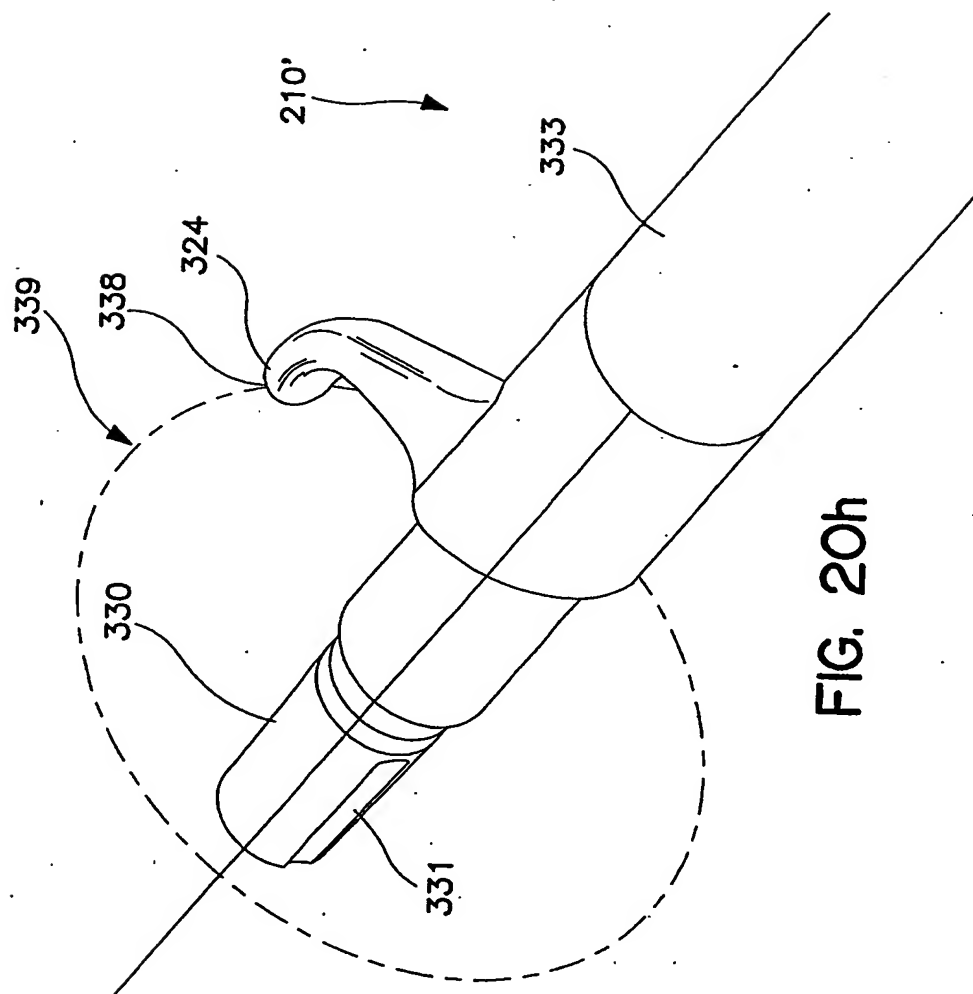


FIG. 20h

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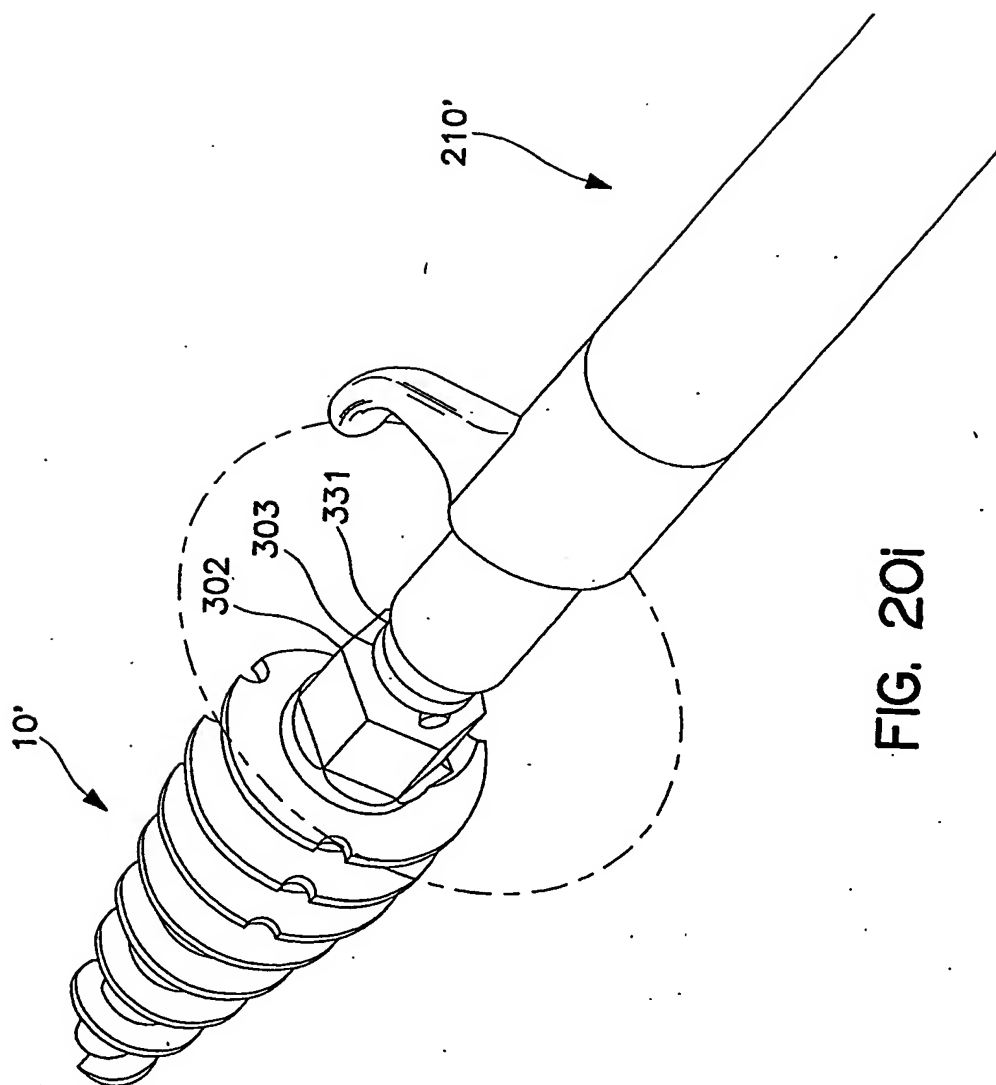


FIG. 20i

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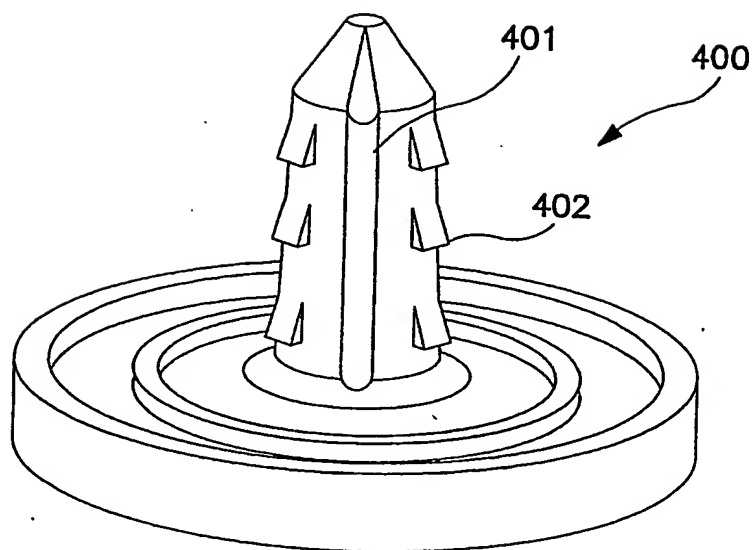


FIG. 21

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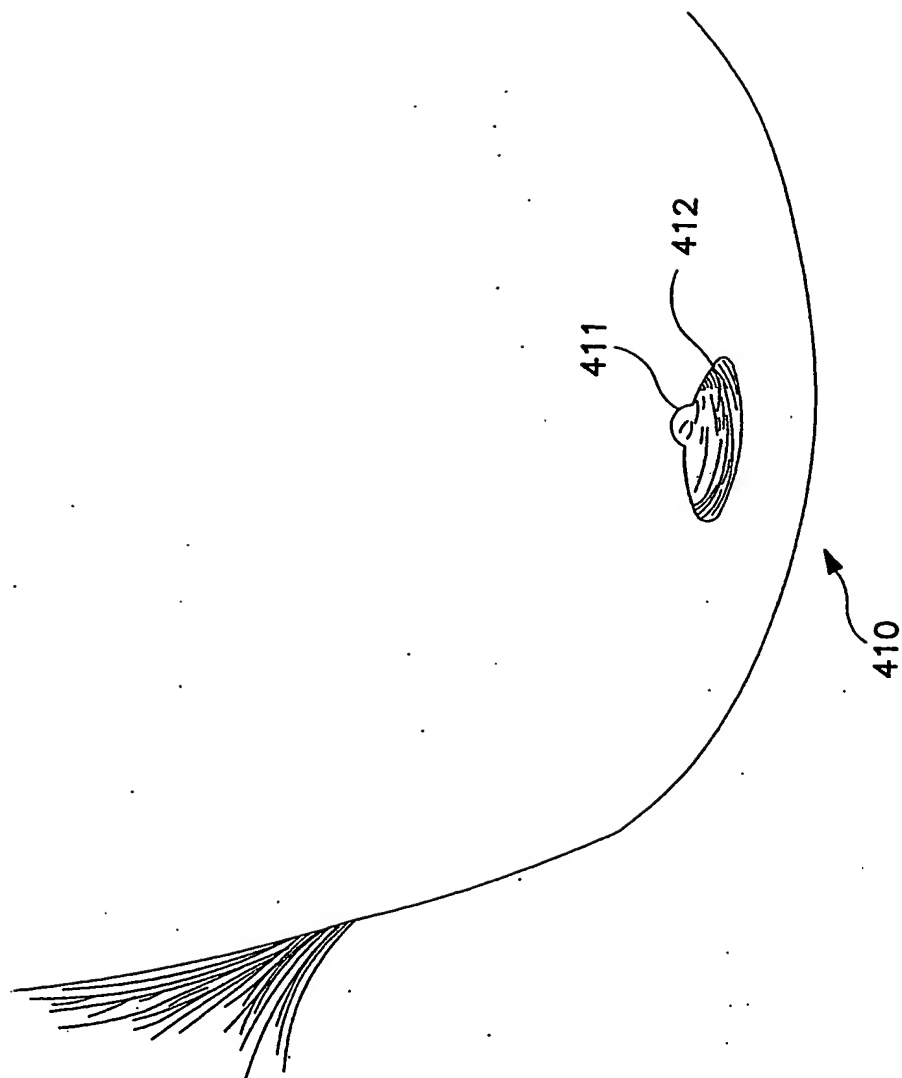


FIG. 22

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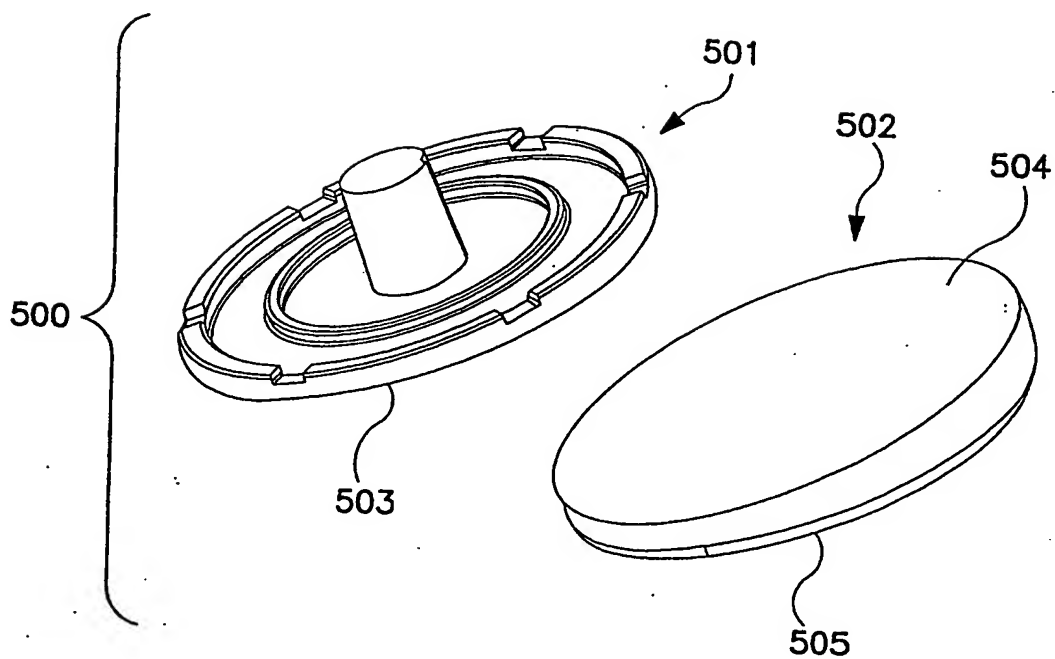


FIG. 23

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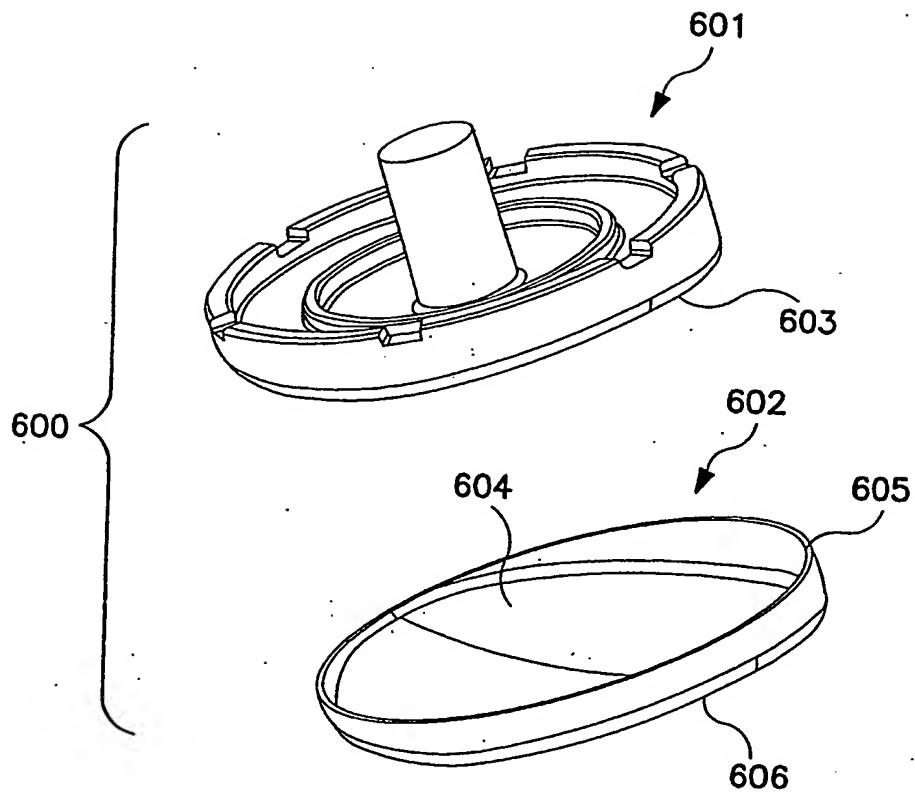


FIG. 24

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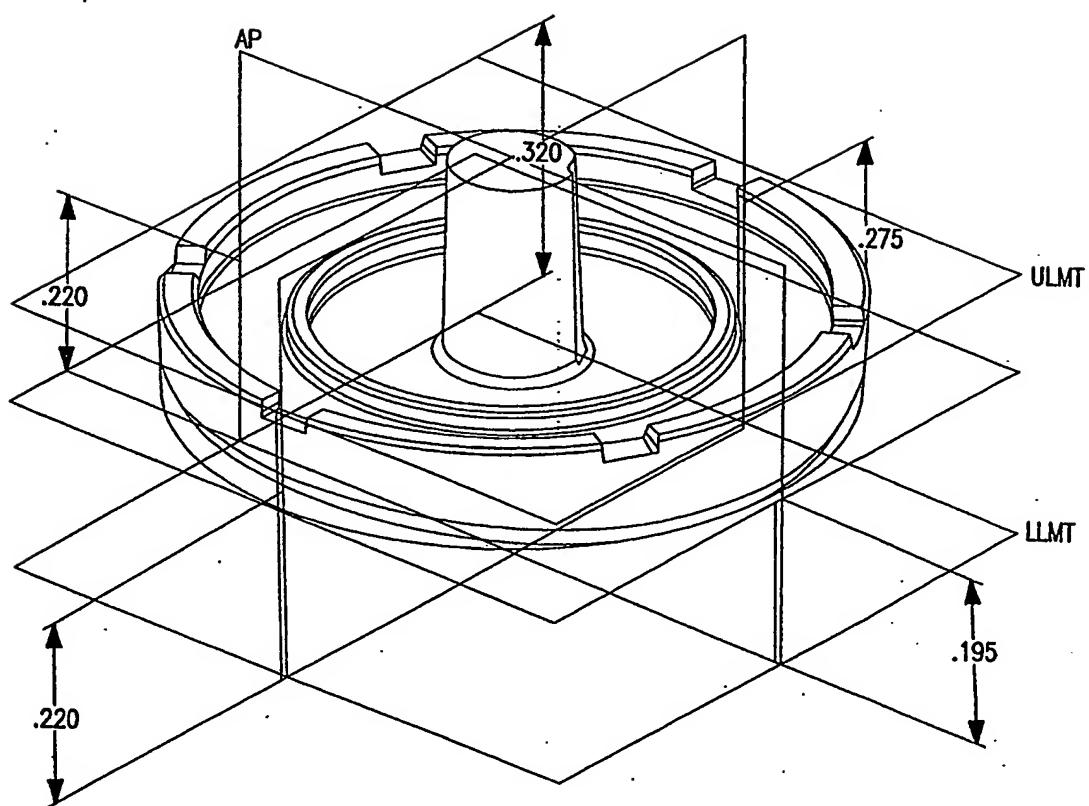


FIG. 25

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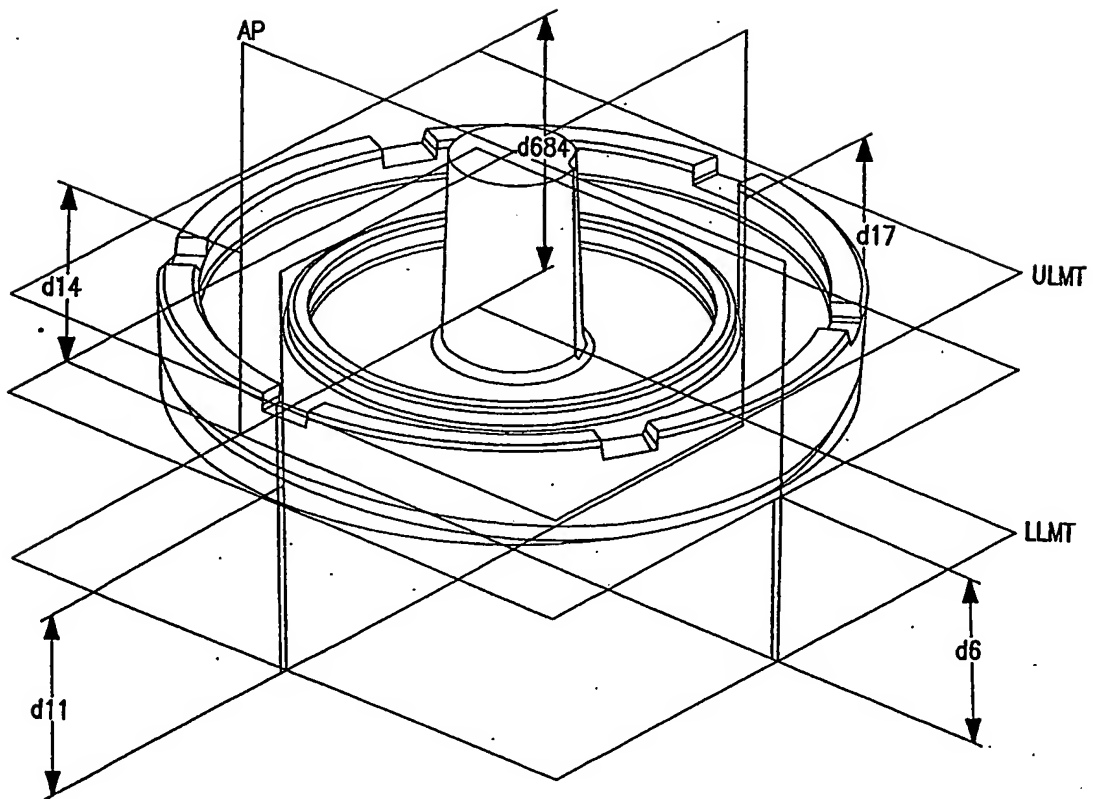
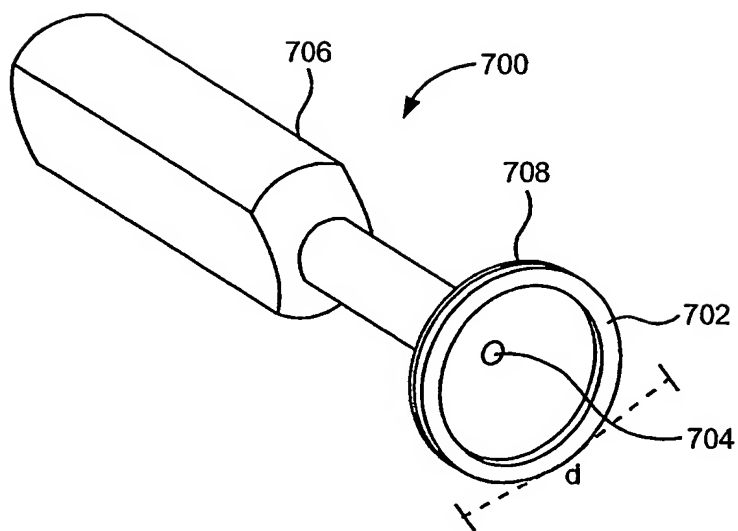


FIG. 26

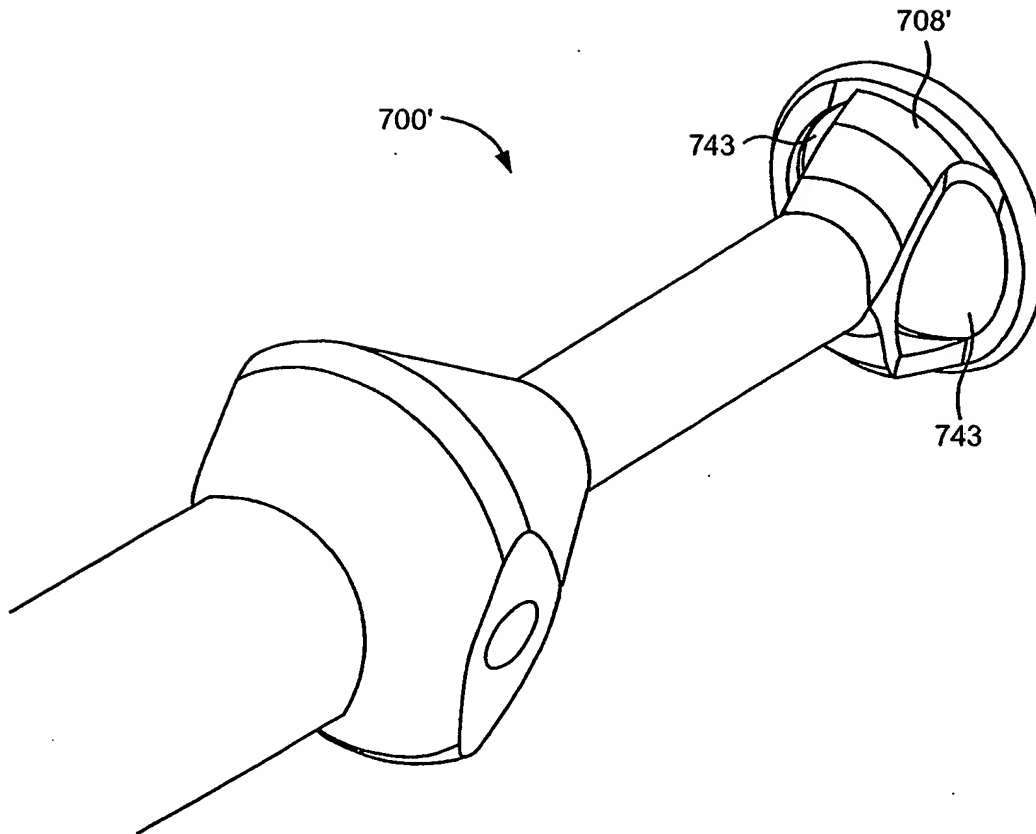
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FIG. 27a



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FIG. 27b



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FIG. 28a

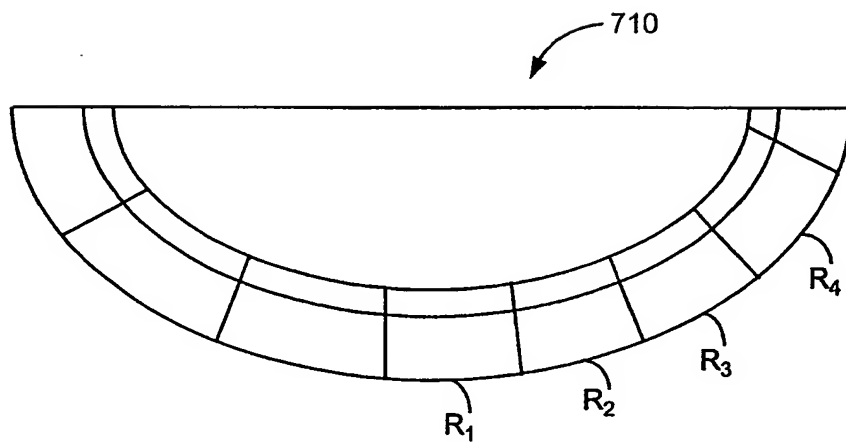
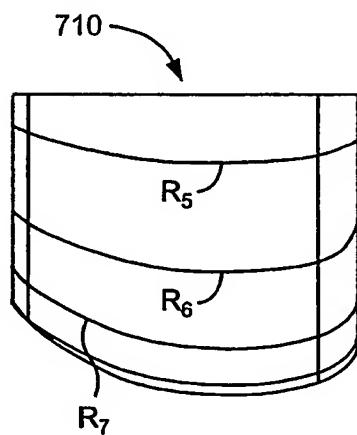
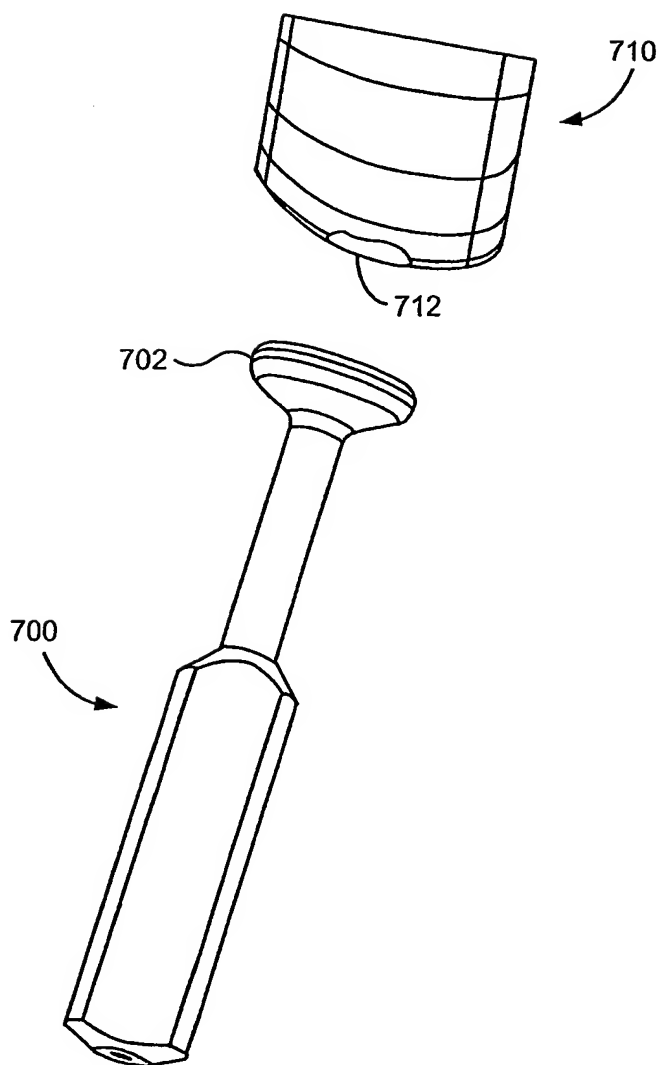


FIG. 28b



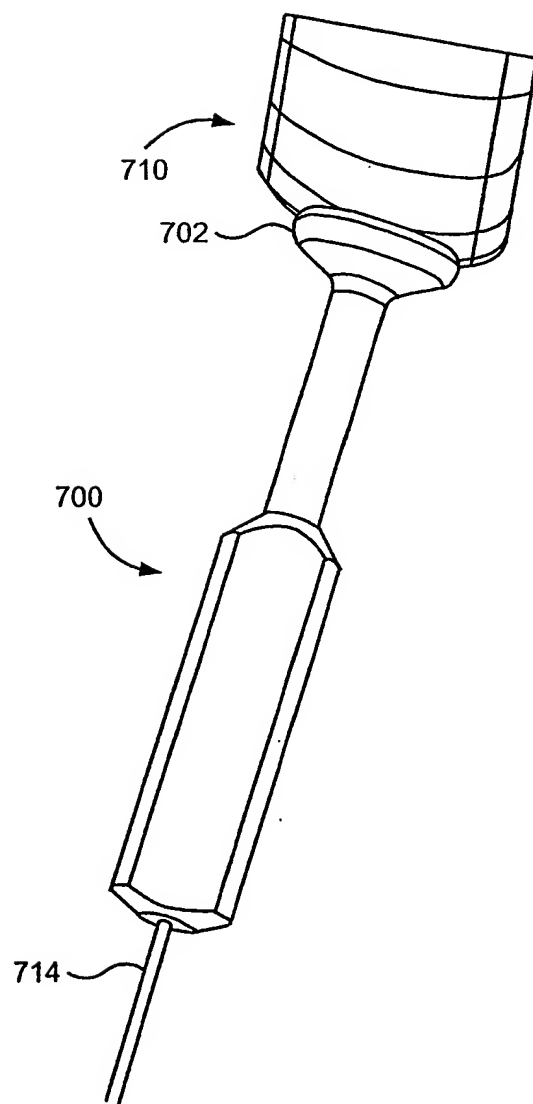
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FIG. 29



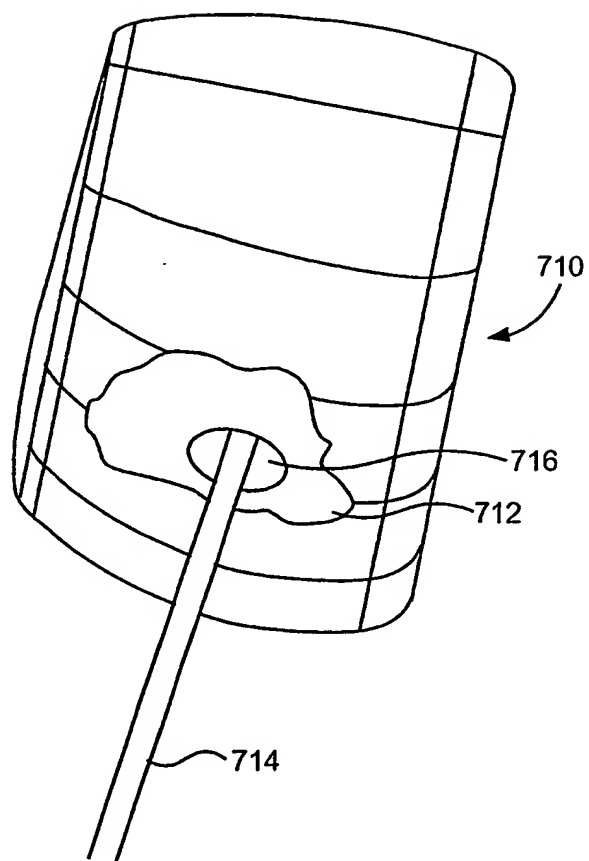
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FIG. 30



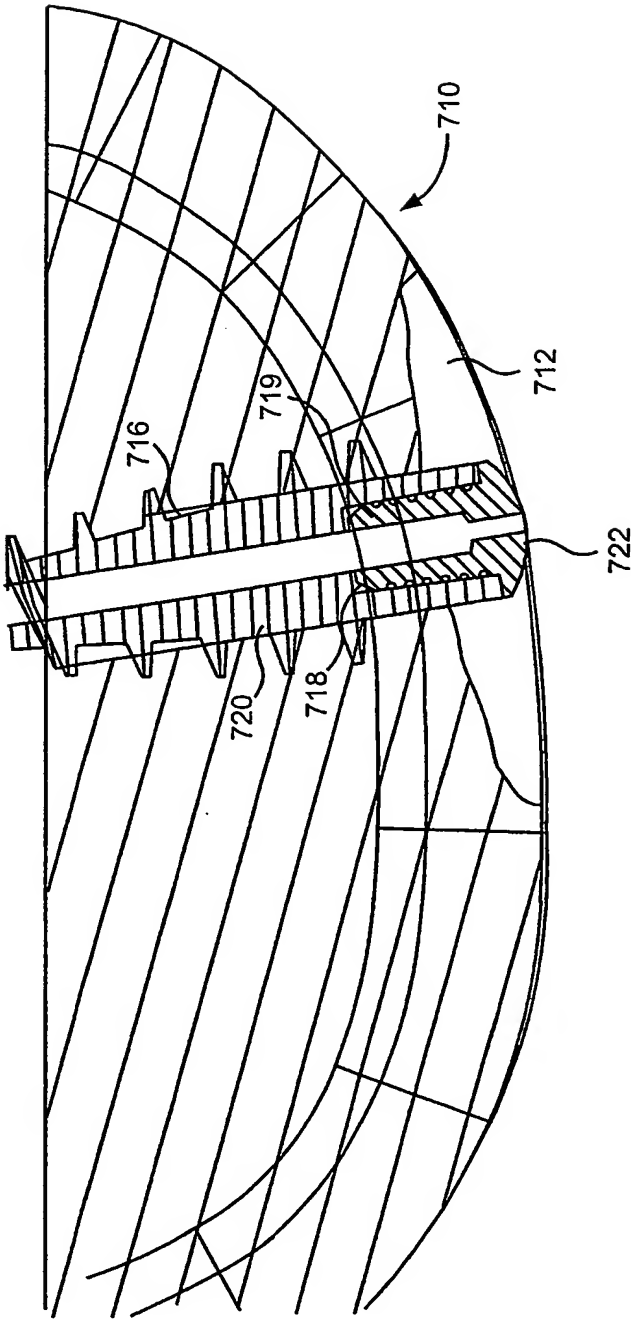
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FIG. 31



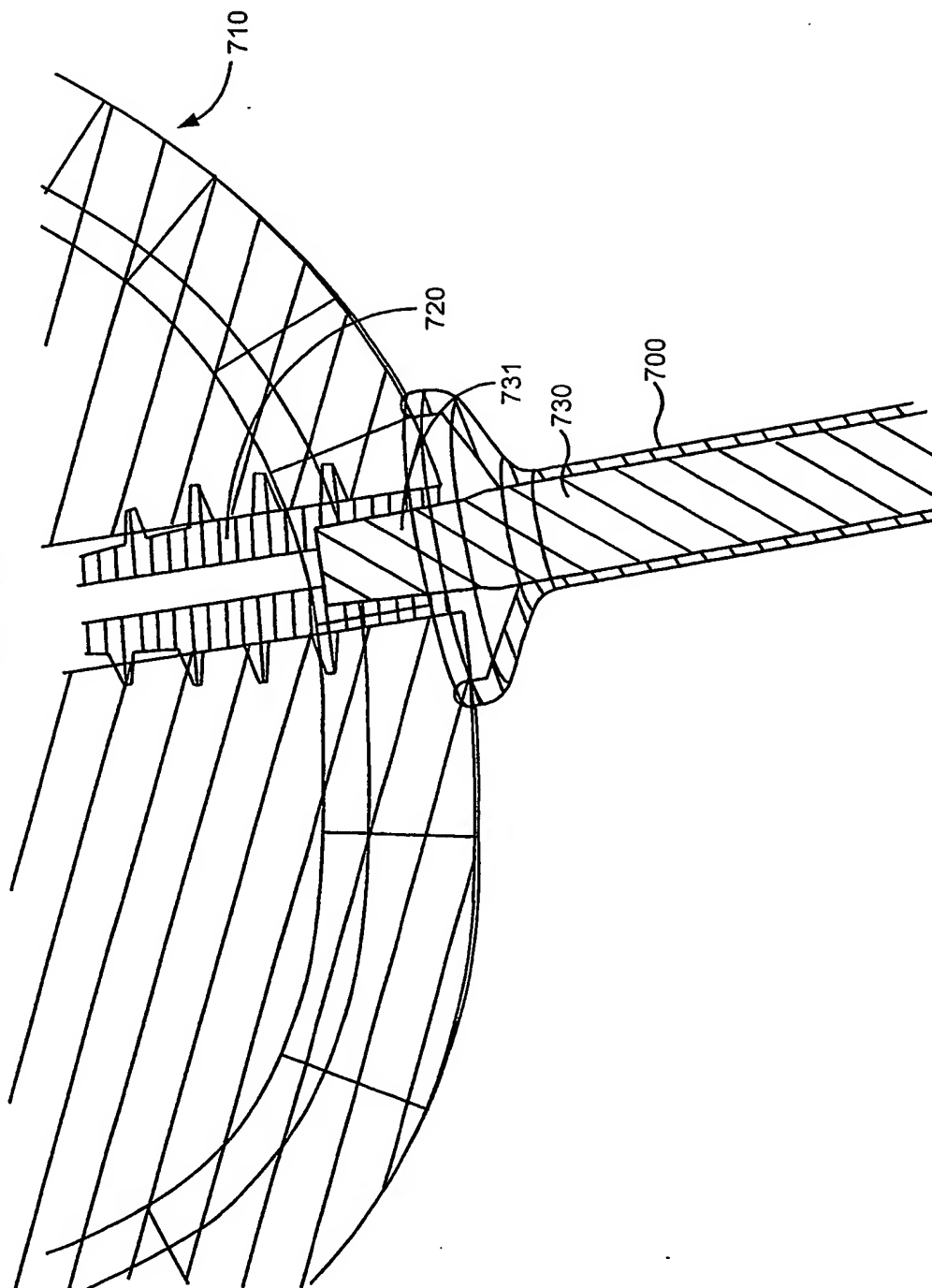
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FIG. 32



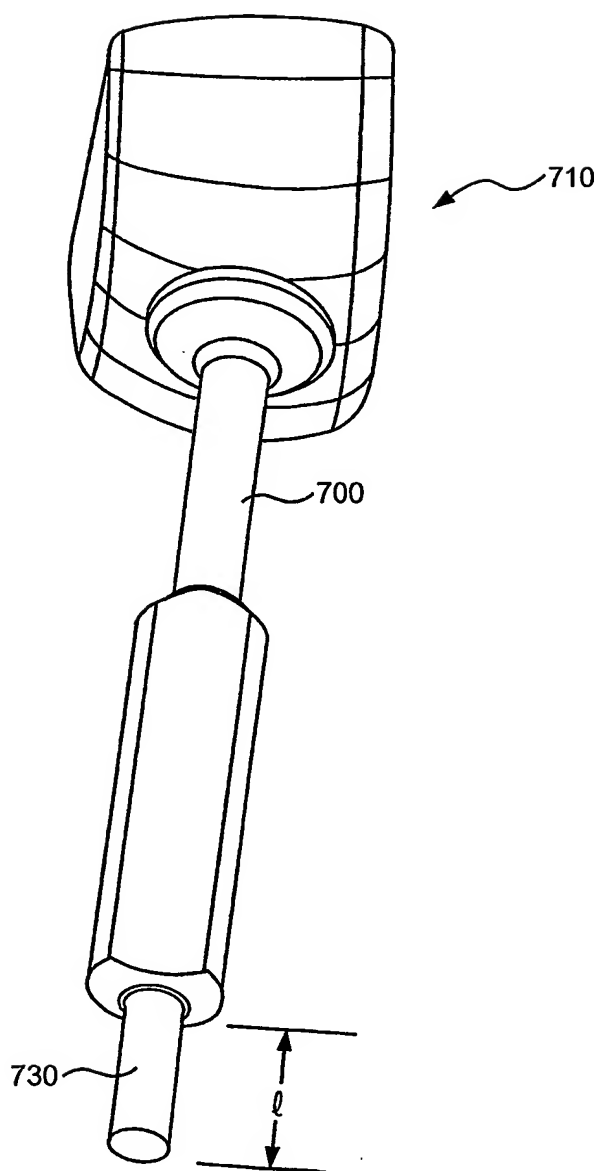
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FIG. 33



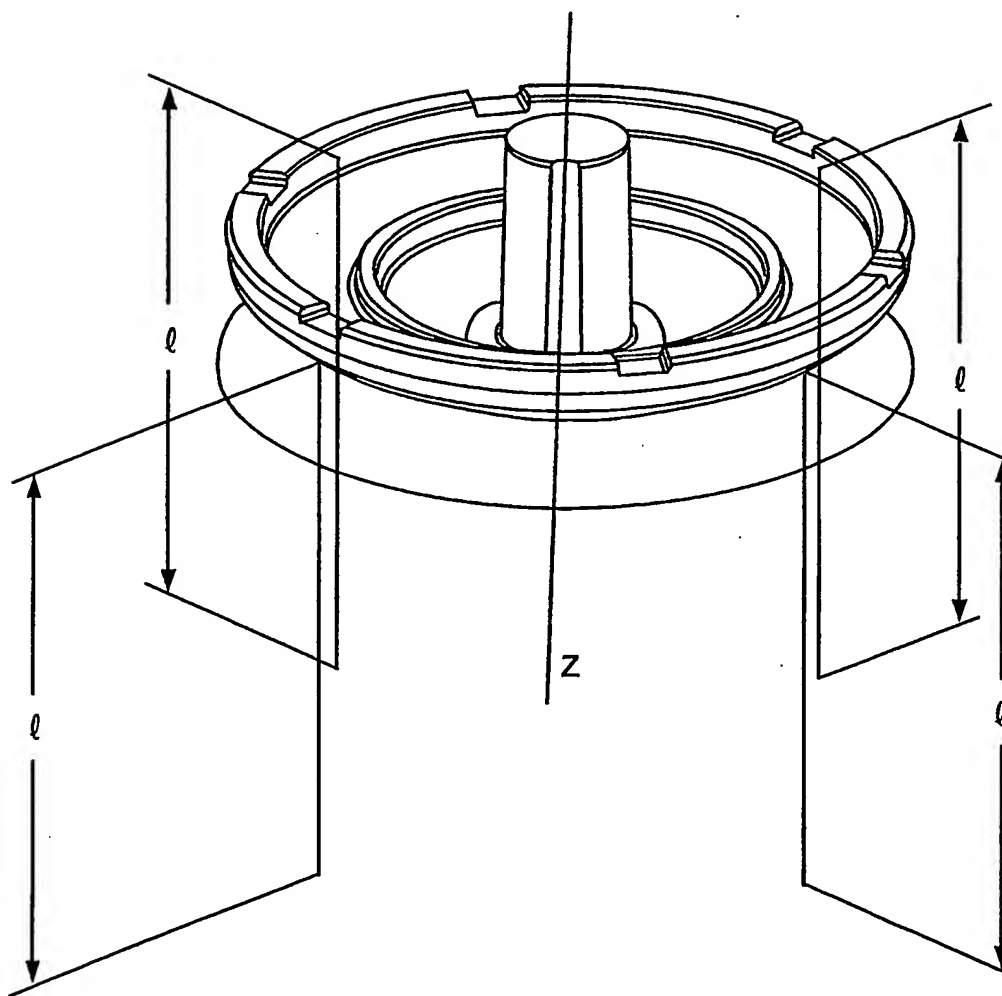
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FIG. 34



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FIG. 35



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FIG. 36

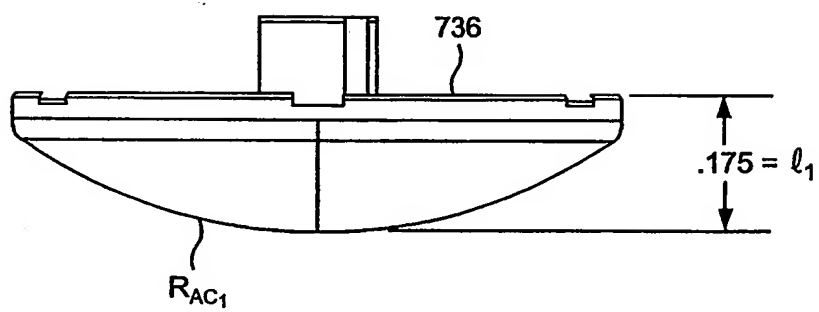
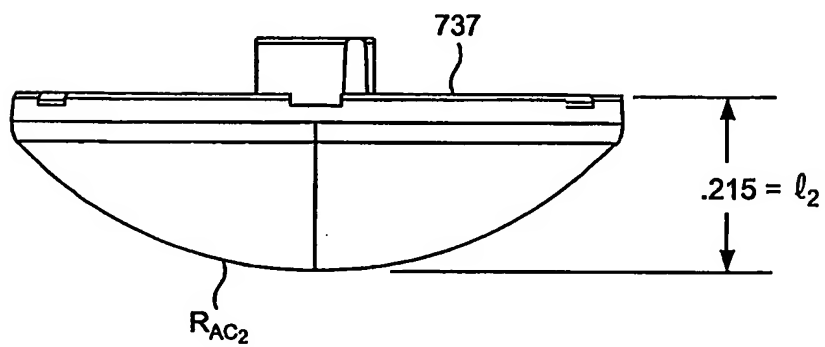
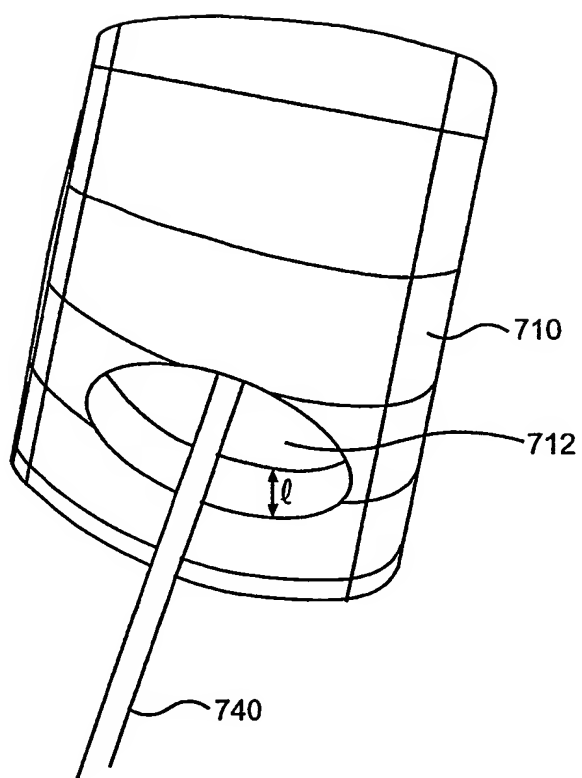


FIG. 37



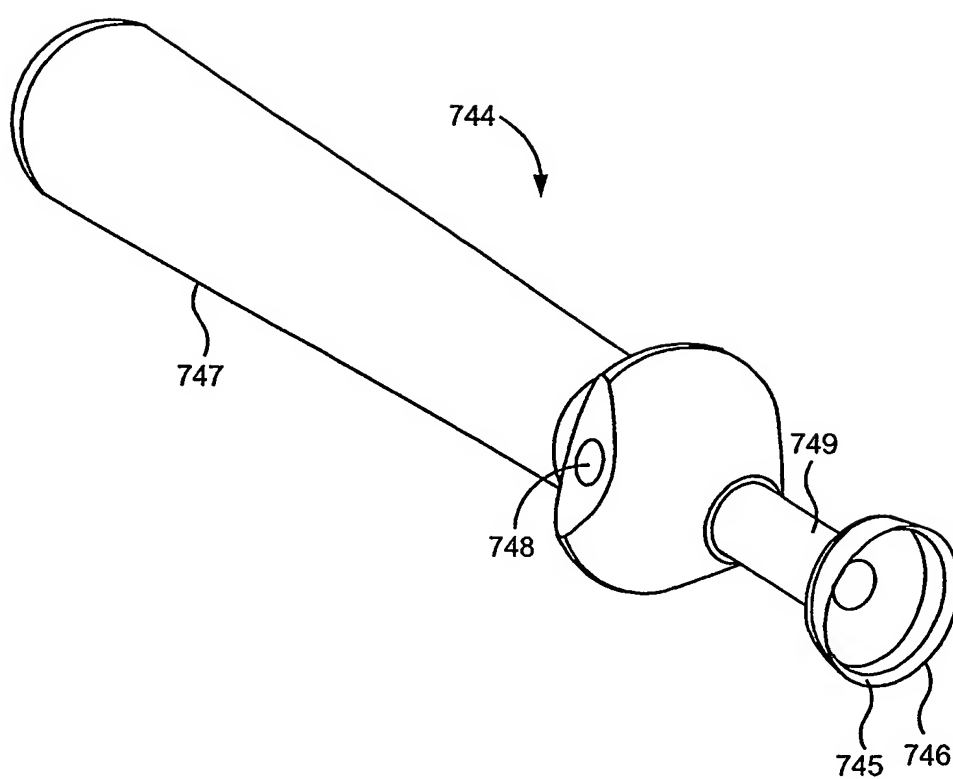
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FIG. 38



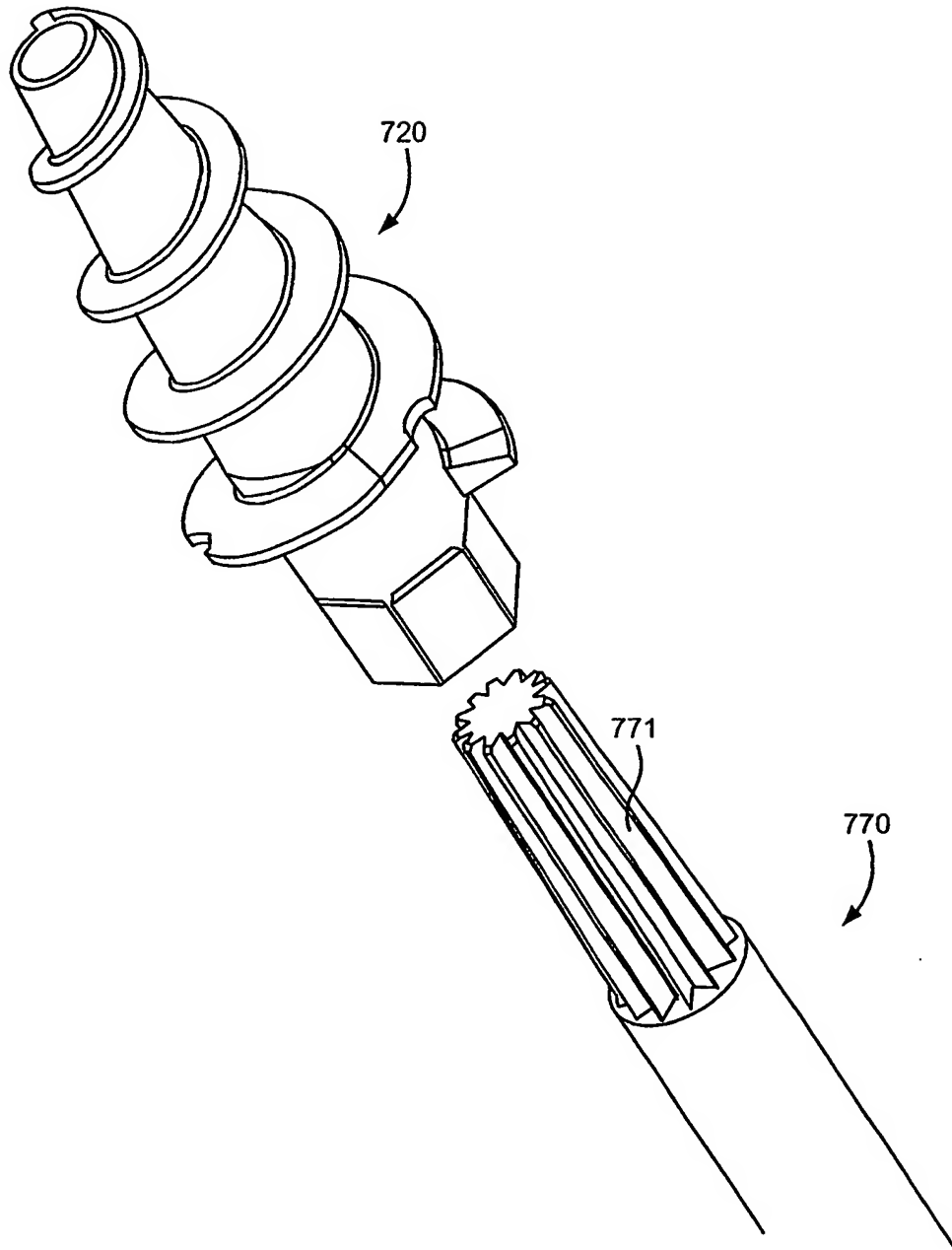
55/75

FIG. 39



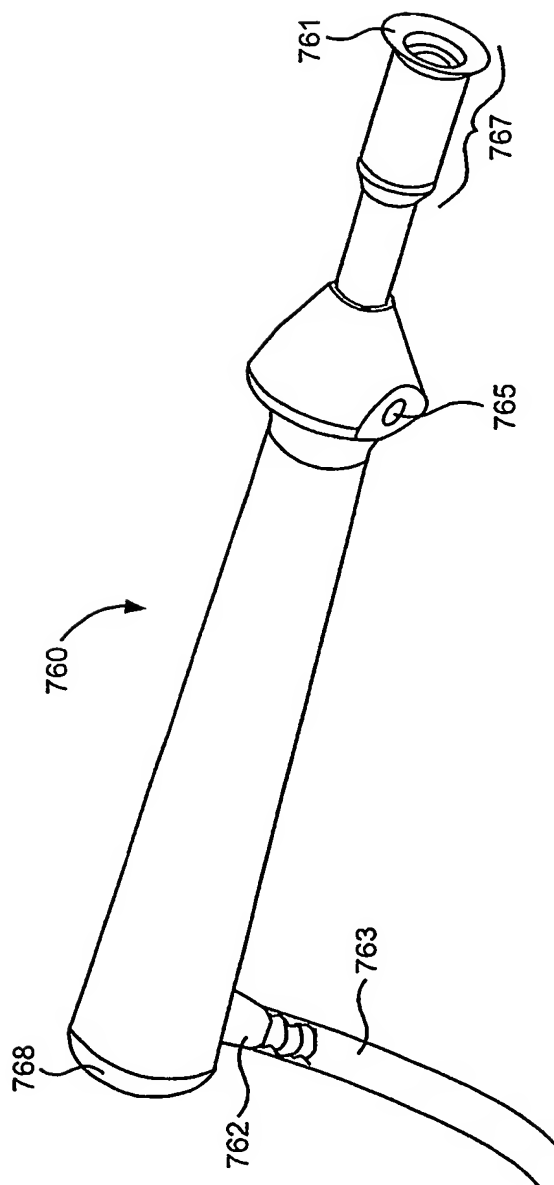
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FIG. 40



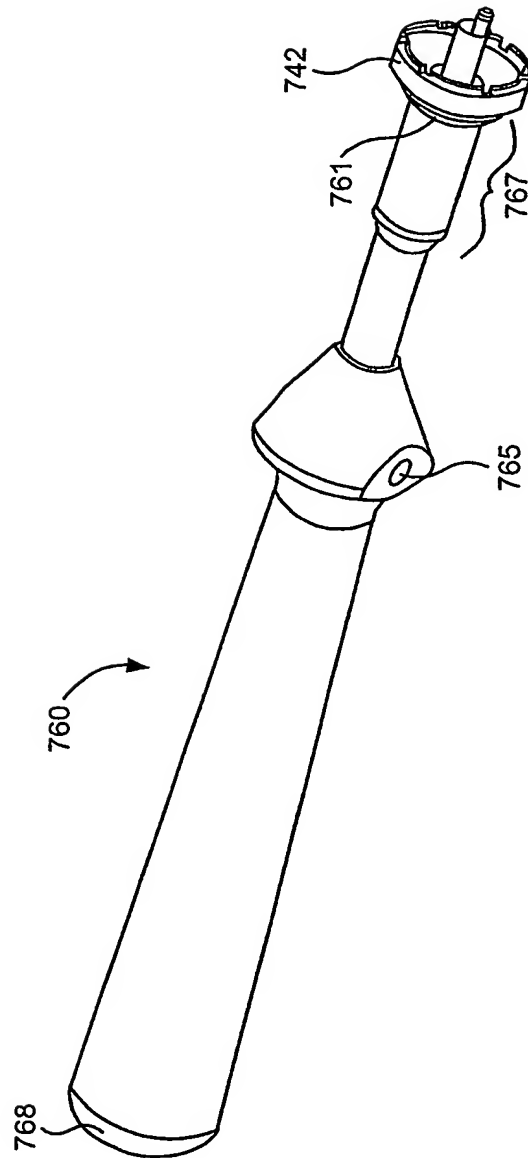
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FIG. 41



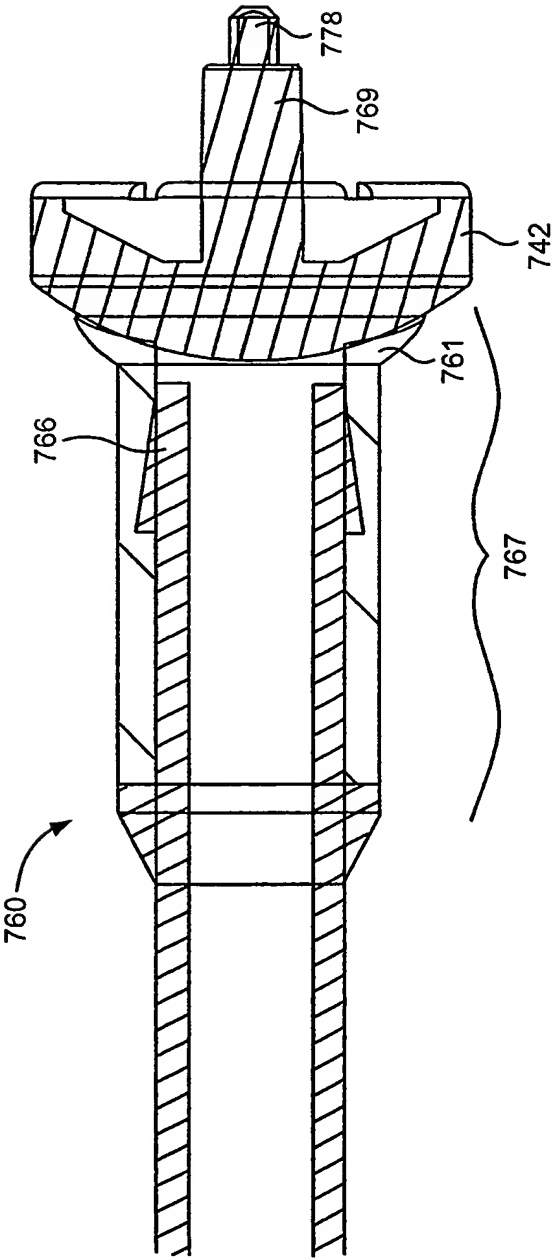
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FIG. 42



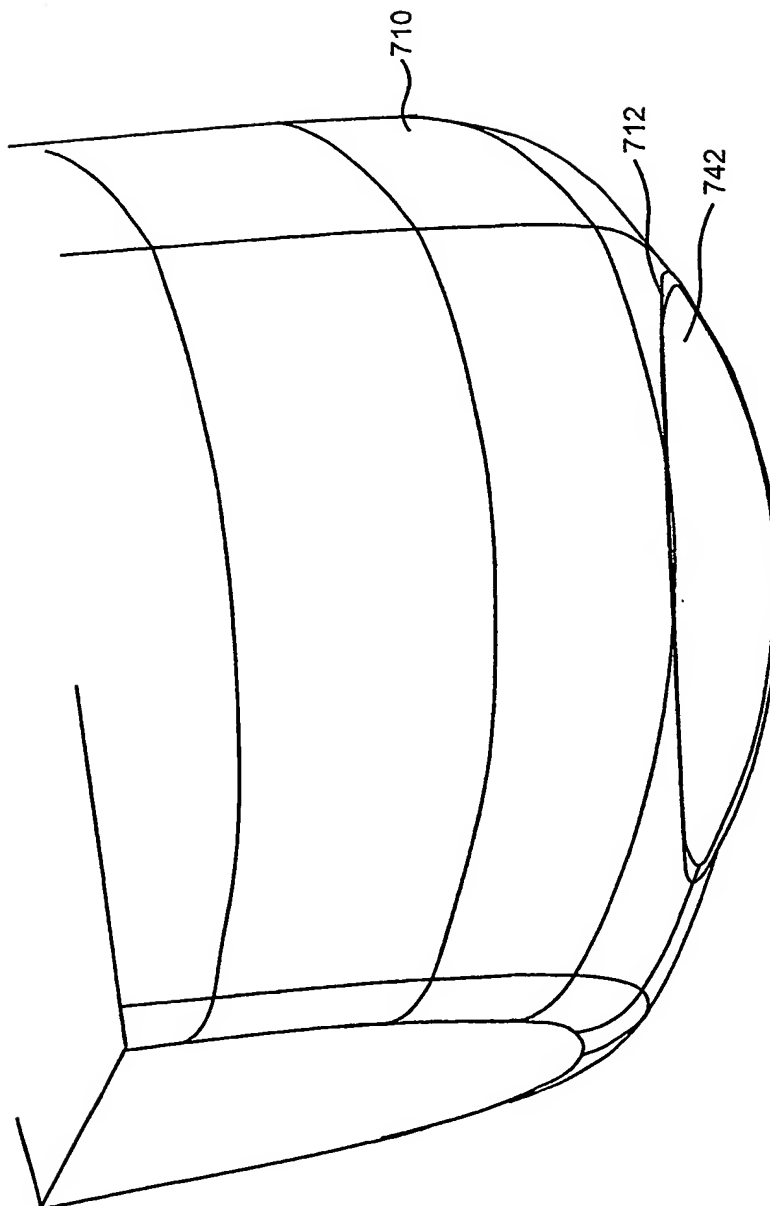
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FIG. 43



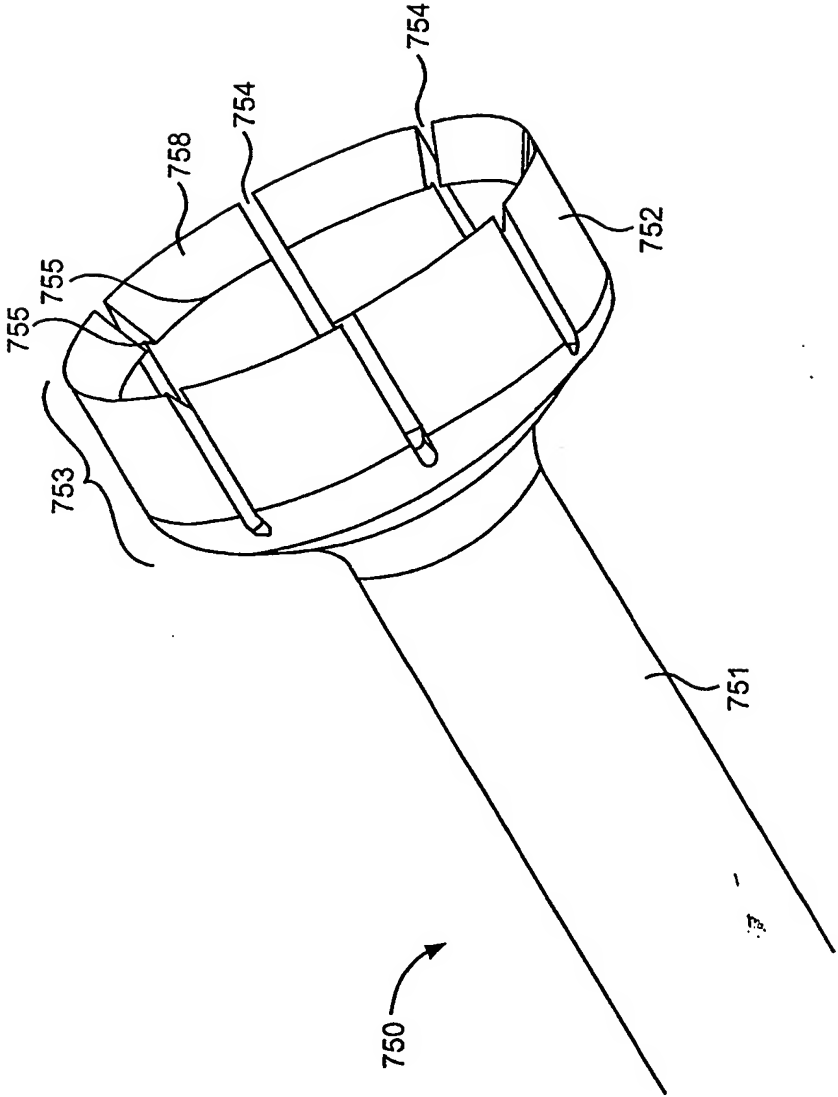
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FIG. 44



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FIG. 45



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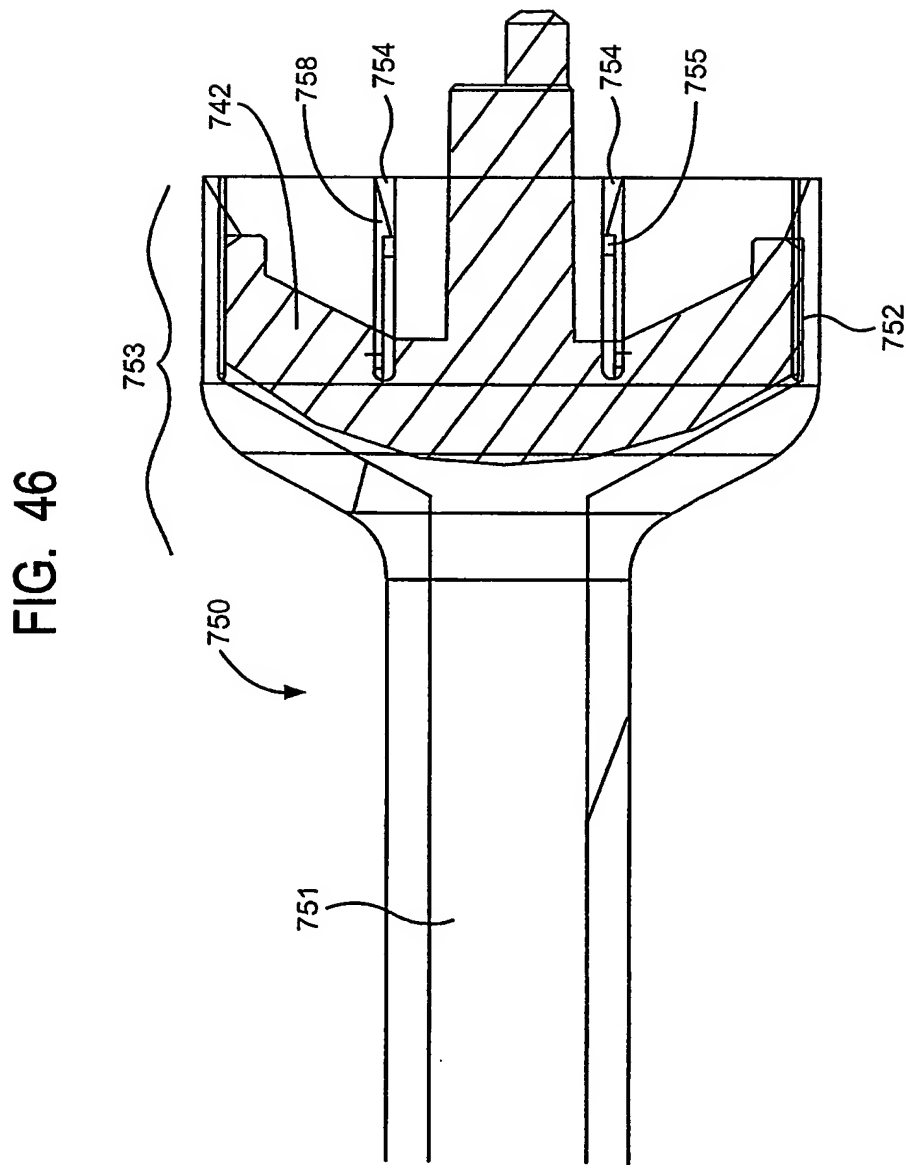


FIG. 47

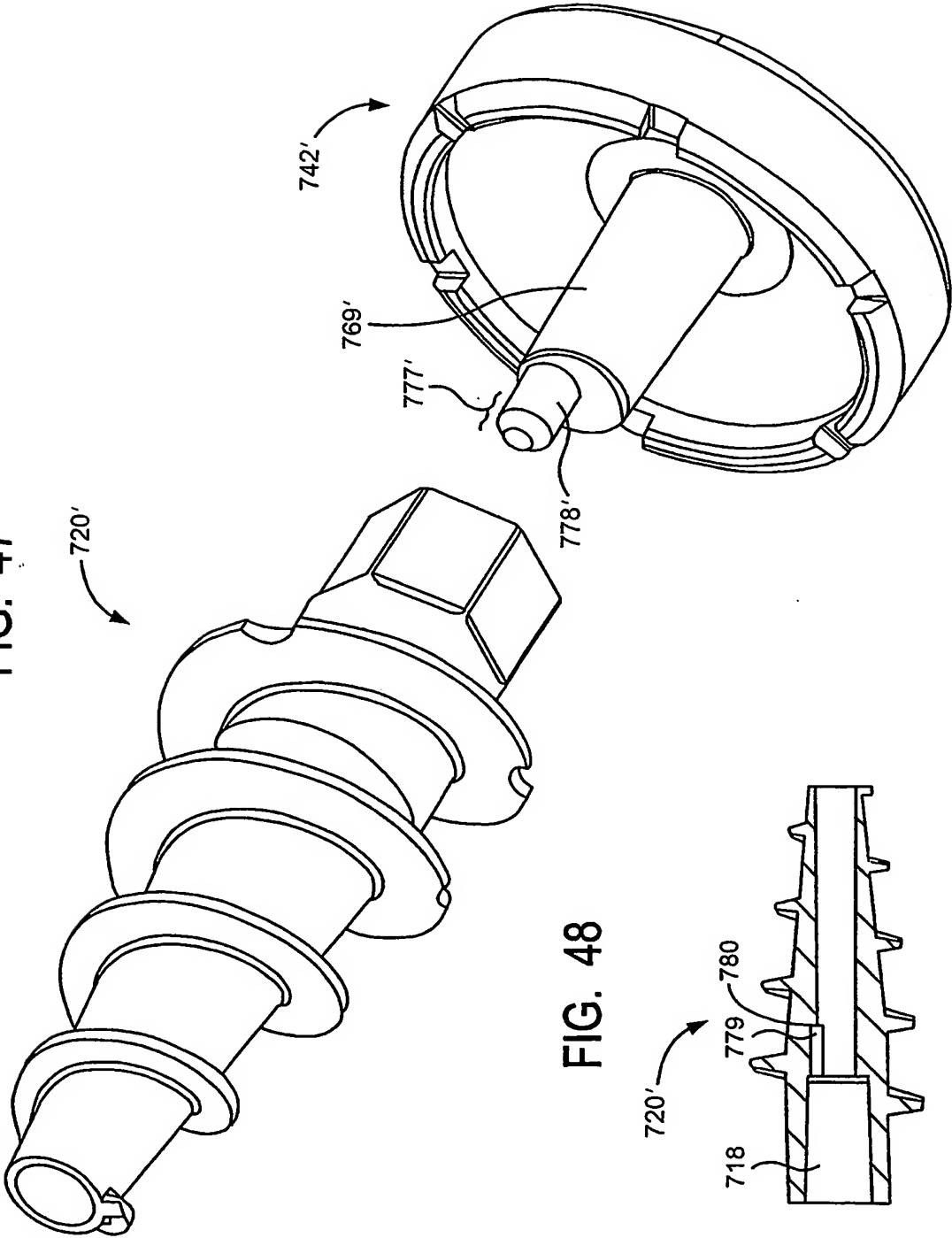


FIG. 48

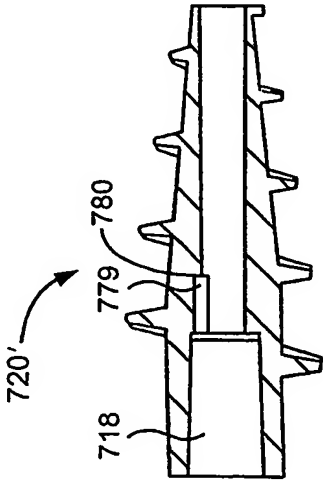
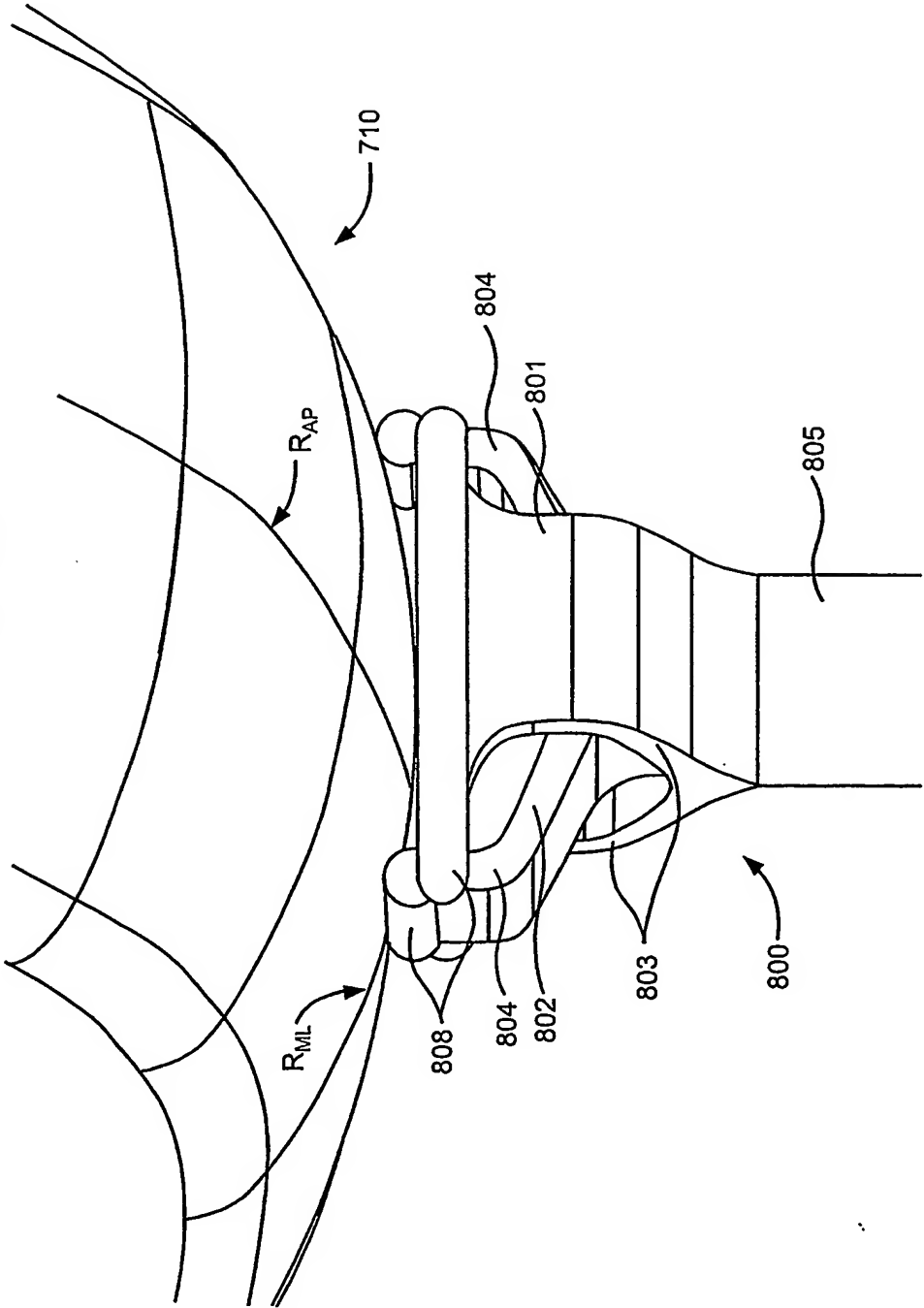


FIG. 49



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FIG. 50

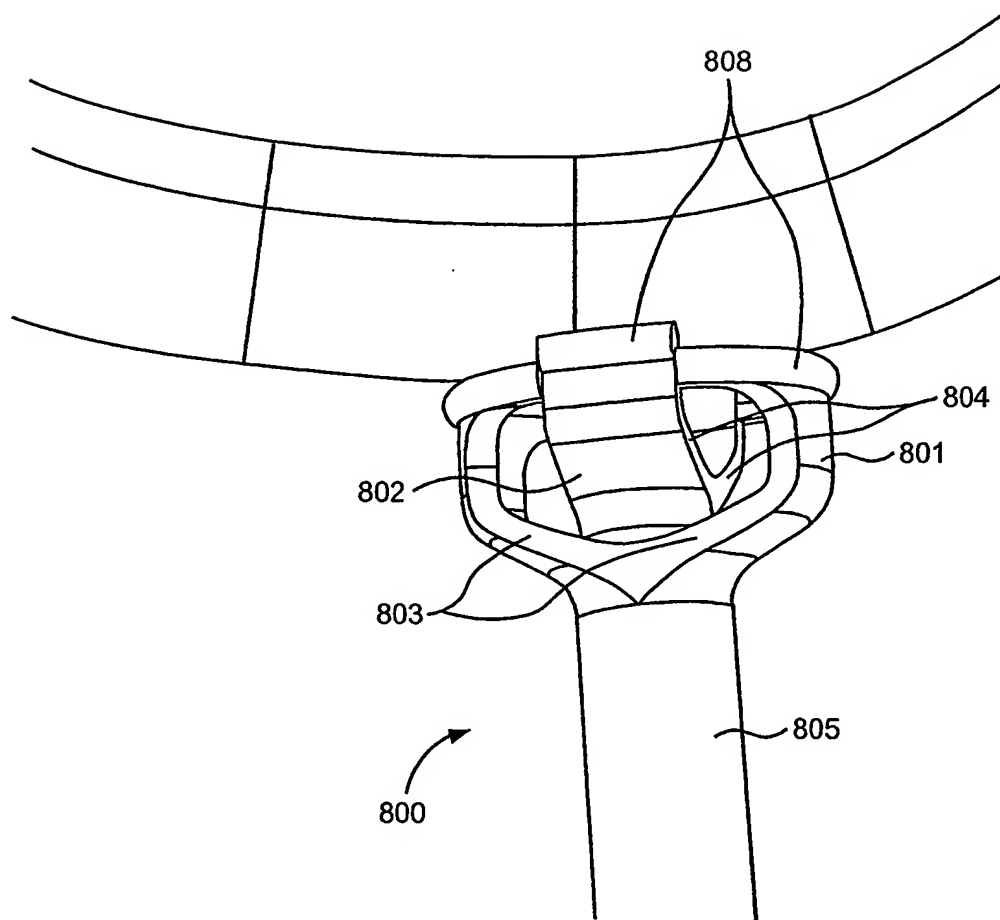
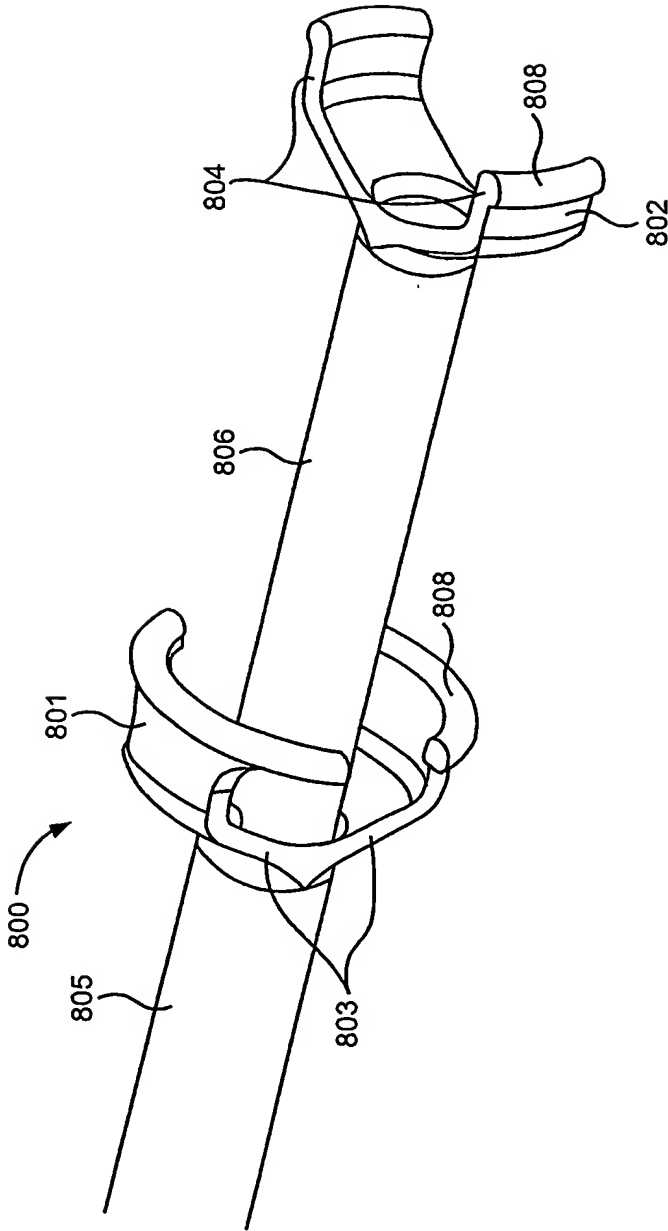
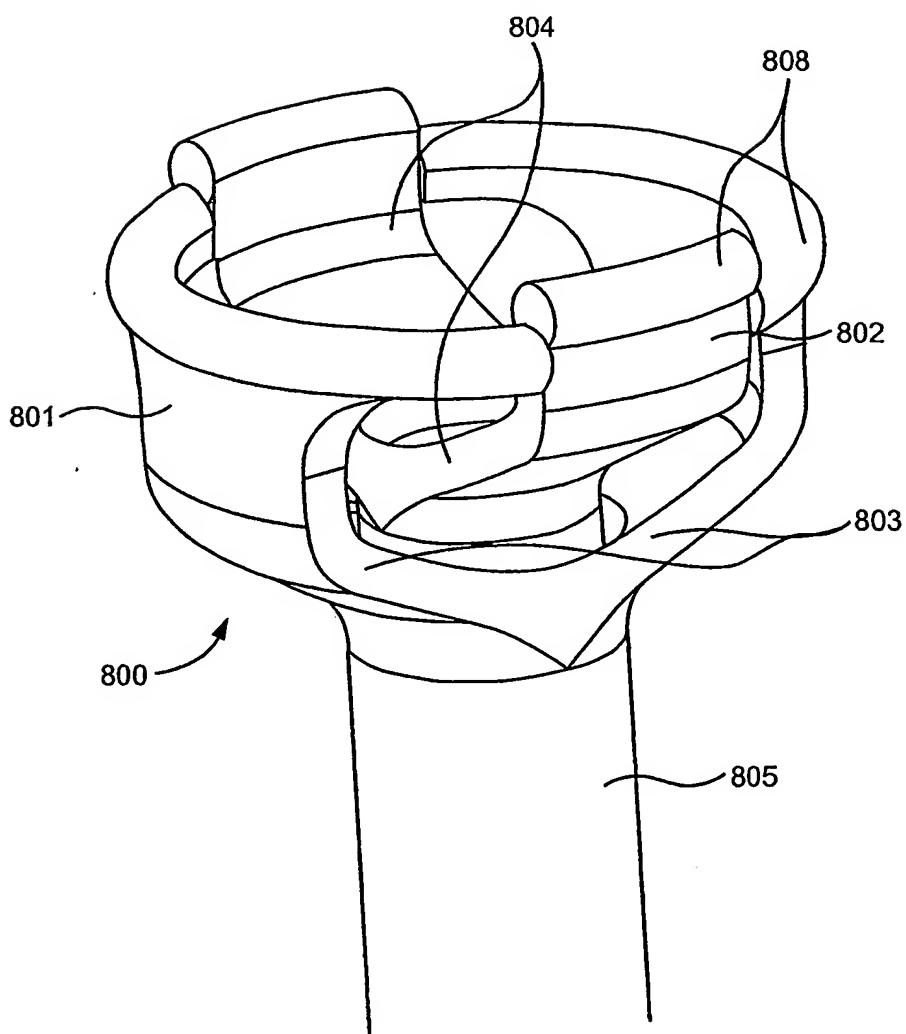


FIG. 51



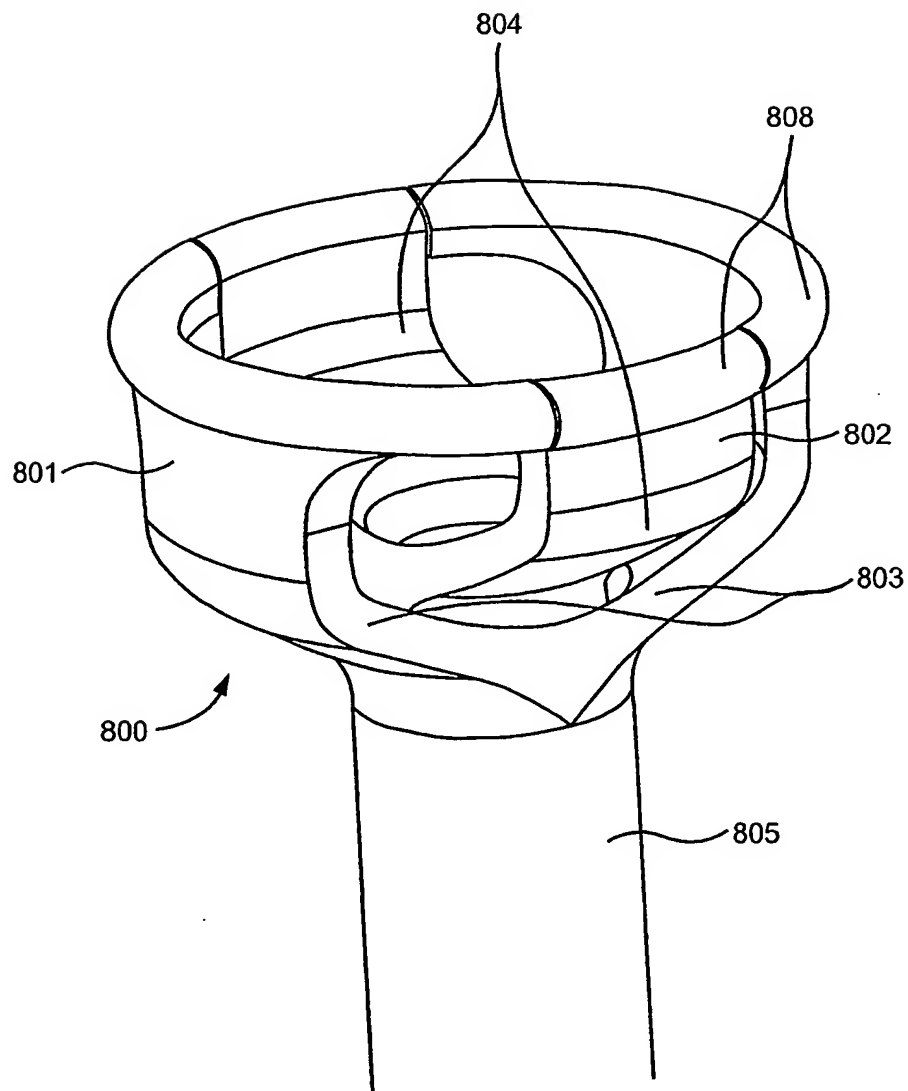
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FIG. 52



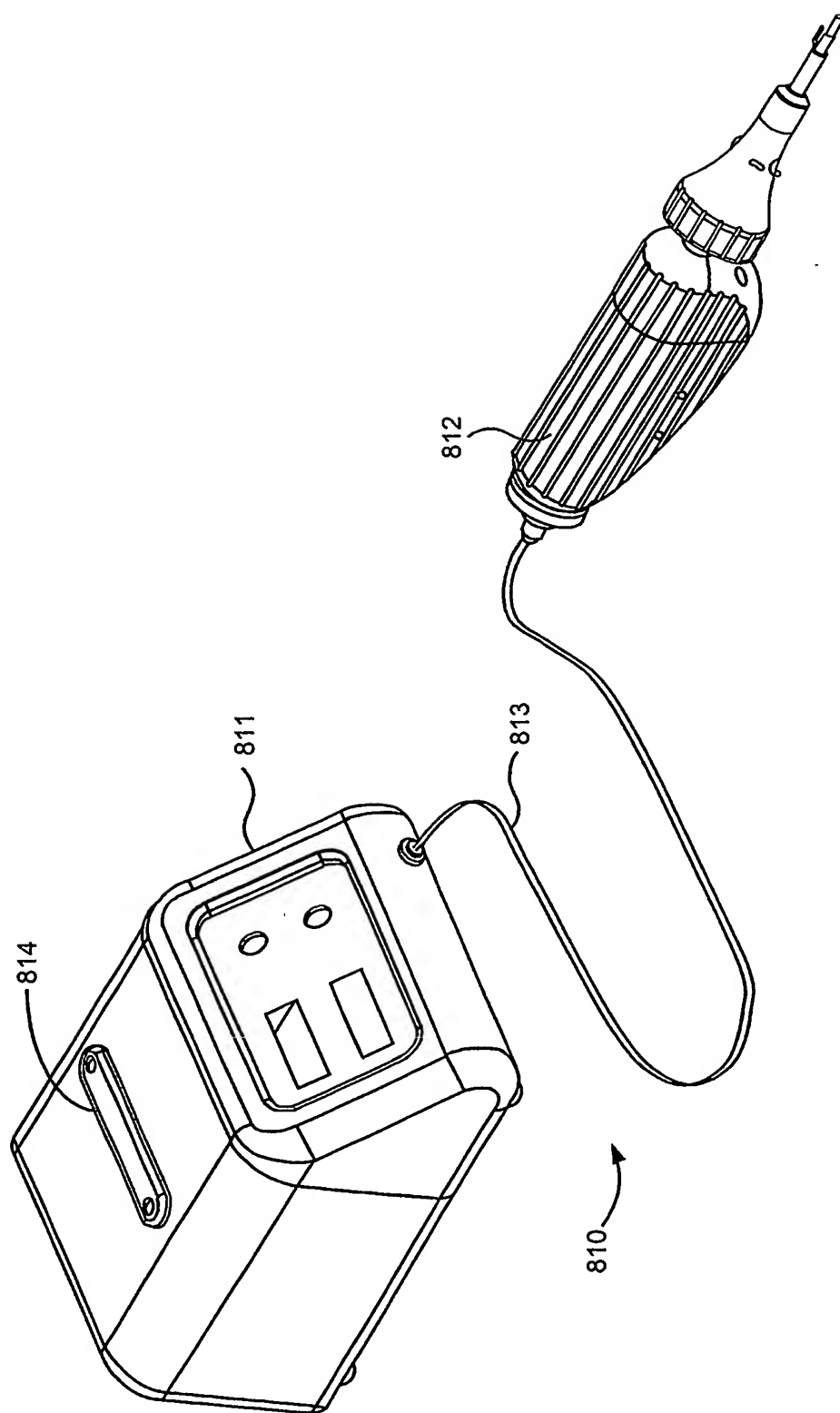
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FIG. 53



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FIG. 54



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FIG. 55

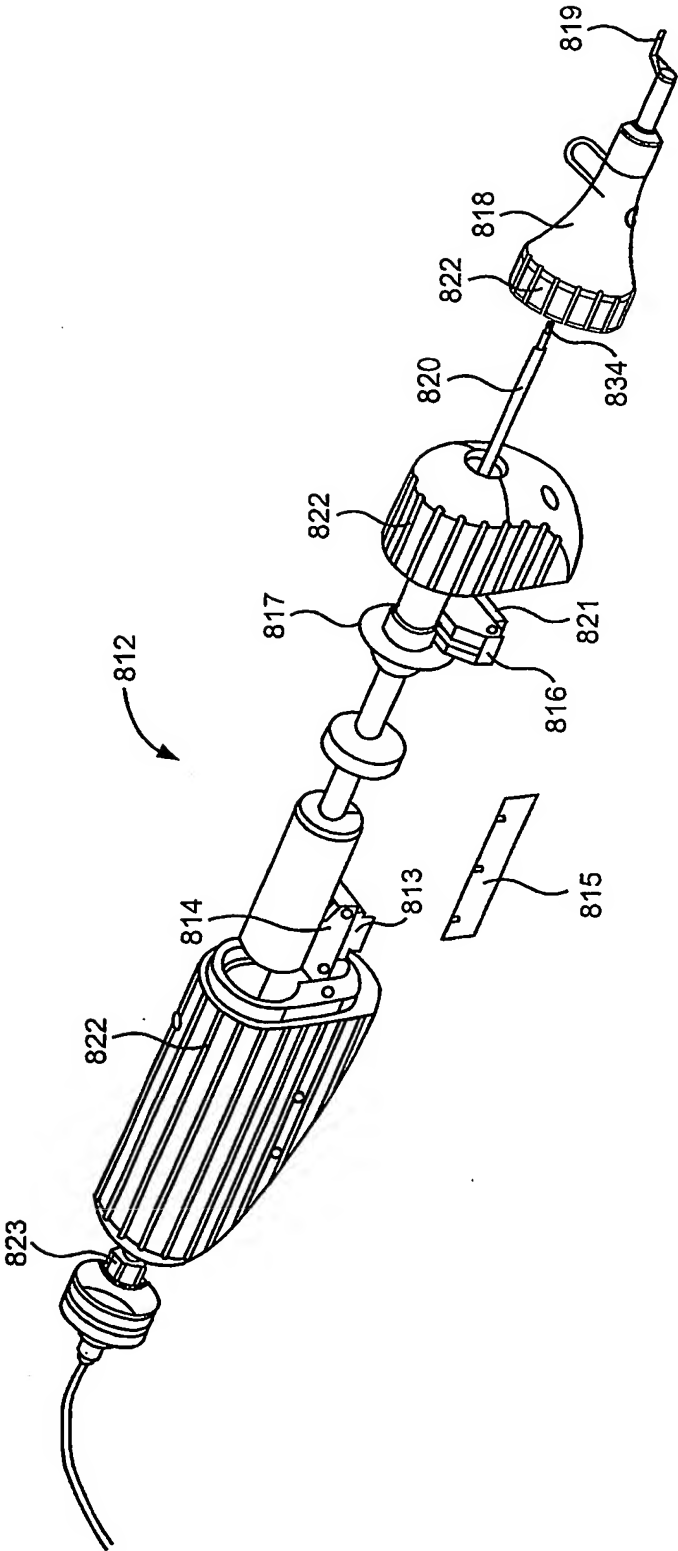


FIG. 55a

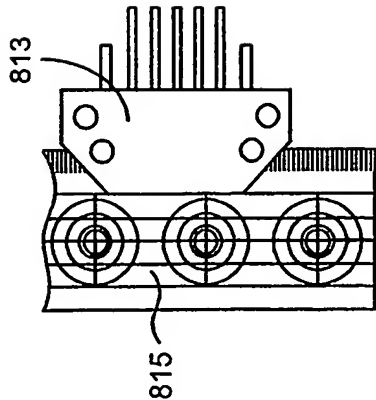


FIG. 55b

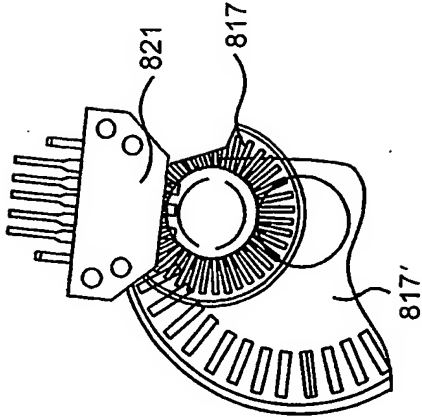


FIG. 55c

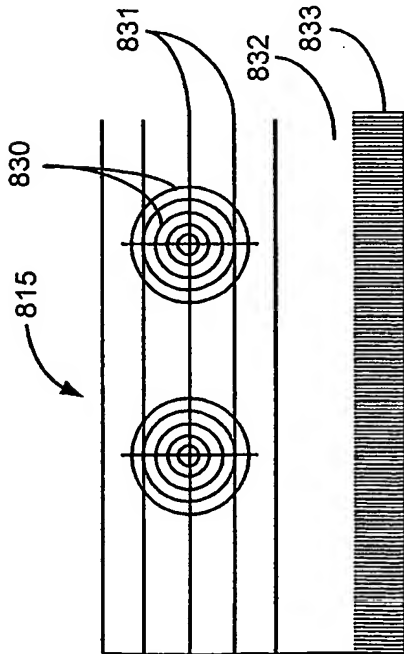
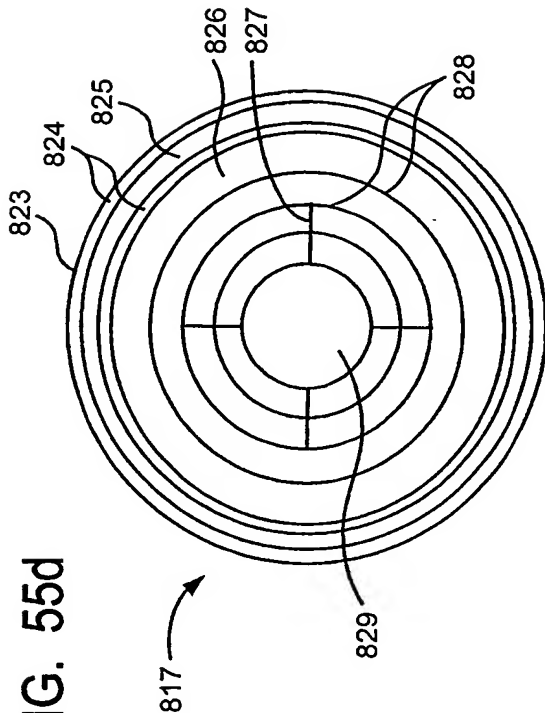
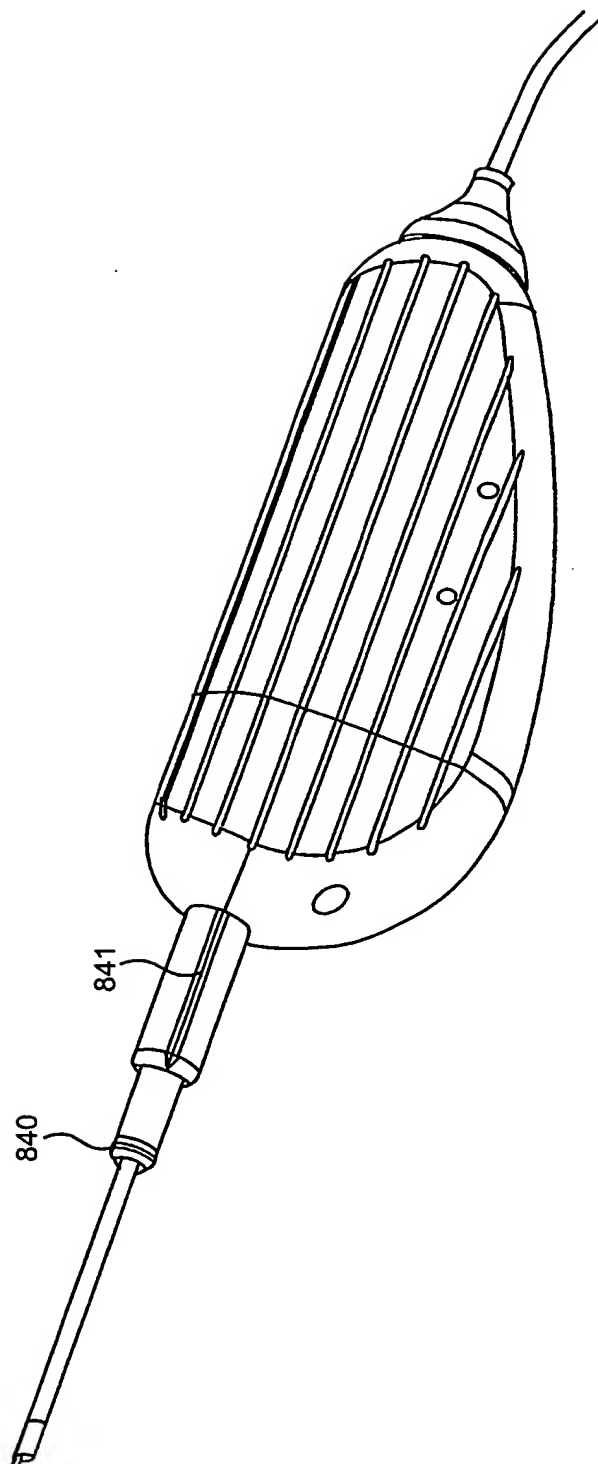


FIG. 55d



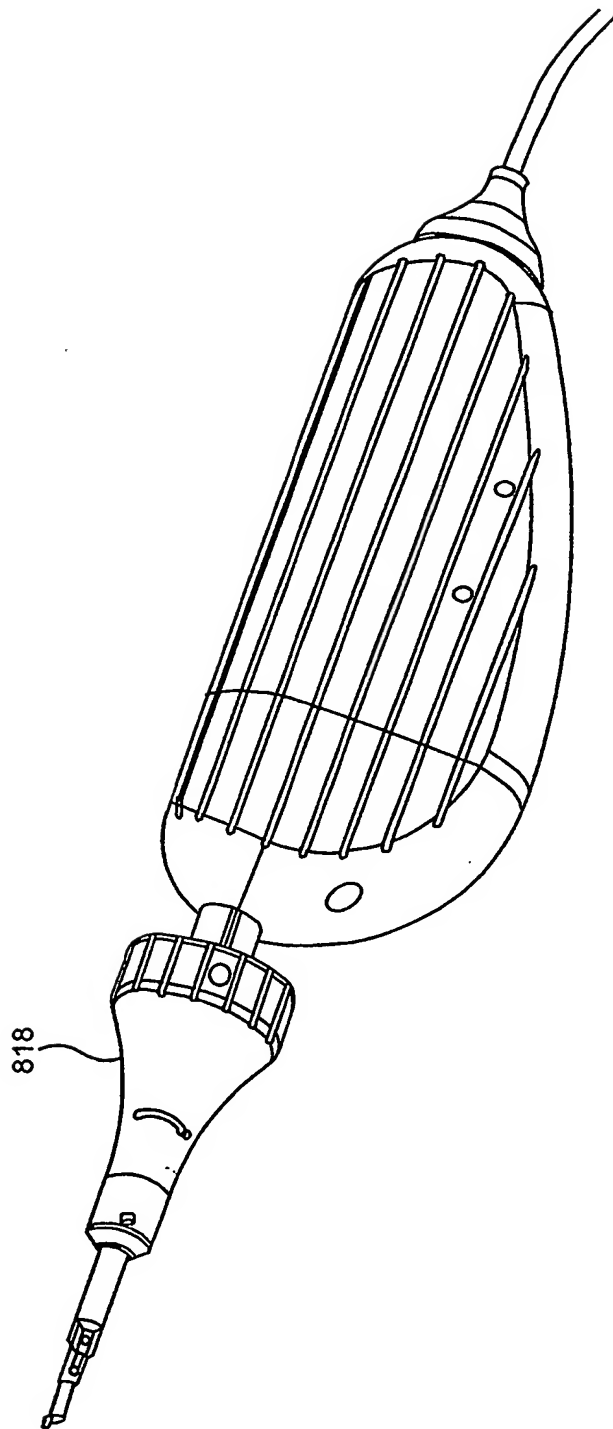
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FIG. 56a



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FIG. 56b



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FIG. 57

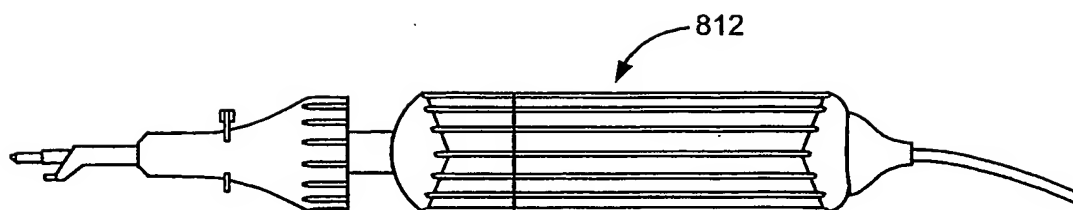


FIG. 58

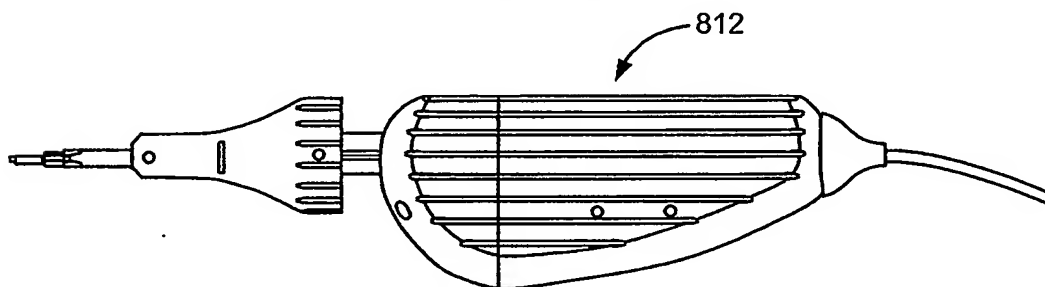


FIG. 59

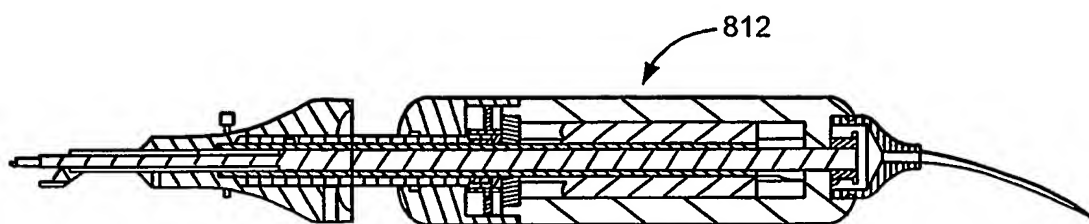
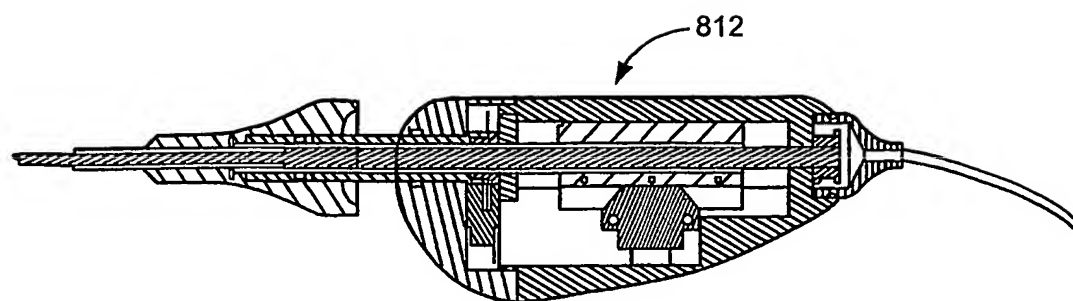
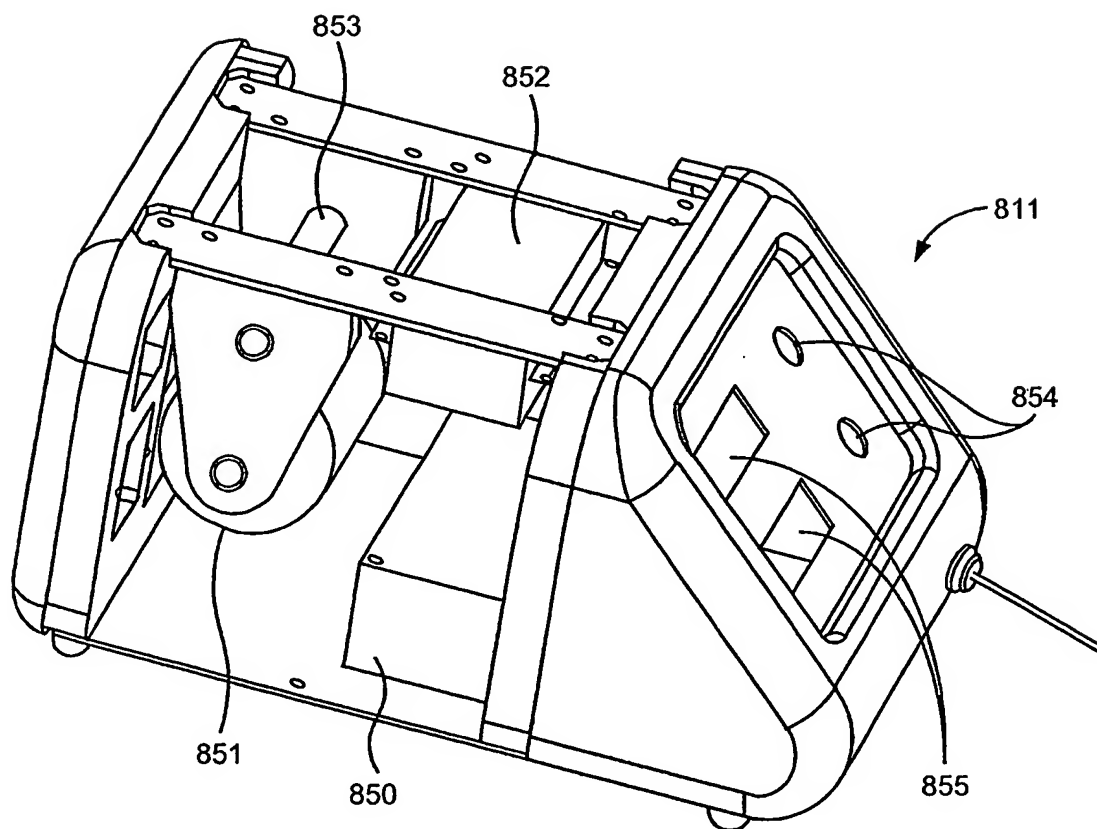


FIG. 60



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FIG. 61



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/48821

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/68

US CL : 606/79, 104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/72, 75, 79, 96, 99, 102, 104

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,632,745 A (SCHWARTZ) 27 May 1997, see entire document.	1-80
A	US 5,782,835 A (HART et al) 21 July 1998, see entire document.	1-80
A	US 6,146,385 A (TORRIE et al) 14 November 2000, see entire document.	1-80
A	US 6,306,142 B1 (JOHANSON et al) 23 October 2001, see entire document.	1-80
A	WO 01/82677 A2 (TALLARIDA et al) 08 November 2001, see entire document.	1-80



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"G" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

29 JUNE 2002

Date of mailing of the international search report

12 NOV 2002

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